MEDICINES ACT
(CHAPTER 285)

MEDICINES (LABELLING) REGULATIONS

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SUBSIDIARY LEGISLATION

MEDICINES (LABELLING) REGULATIONS

ARRANGEMENT OF REGULATIONS

SUBSIDIARY LEGISLATION

Regulations made under section 81(1)

MEDICINES (LABELLING) REGULATIONS

Commencement: 1st July 2010

Citation

1. These Regulations may be cited as the Medicines (Labelling) Regulations.

Interpretation

2. In these Regulations, unless the context otherwise requires —

"appropriate non-proprietary name" means —

(a) where the medicinal product or ingredient is described in a monograph in a specified publication which was last published before the date on which the medicinal product was supplied or dispensed, any name or abbreviation of that name or synonym at the head of that monograph;

(b) where the medicinal product or ingredient is not described in a monograph in a specified publication but has an international non-proprietary name, that international non-proprietary name; or

(c) where the medicinal product or ingredient is not described in a monograph in a specified publication and does not have an international non-proprietary name, the accepted scientific name or other name descriptive of the true nature of the medicinal product or ingredient;

"appropriate quantitative particulars" means —

(a) the quantity of each active ingredient, identified by its appropriate non-proprietary name, in each dosage unit of the medicinal product expressed in terms of weight, volume, capacity or units of activity; or

(b) where there is no dosage unit, the quantity of each active ingredient identified by its appropriate non-proprietary name, in the container of the medicinal product expressed in terms of weight, volume, capacity or units of activity or percentage by weight or volume of the total quantity;

"dispensed medicinal product" means —

(a) a medicinal product supplied by a doctor or dentist to his patient or to a person under whose care that patient is; or

(b) a medicinal product dispensed by a pharmacist in any premises registered under the Act for carrying on a retail pharmacy business;

"expiry date" means the date after which, or the month and year after the end of which, a medicinal product should not be used, or the date before which or the month and year before the beginning of which, a medicinal product should be used;

"international non-proprietary name" means a name which has been selected by the World Health Organisation as a recommended international non-proprietary name and in respect of which the Director-General of the World Health Organisation has given notice to that effect in the WHO Chronicle;

"proprietary designation" means the word or words used in connection with the sale or supply of medicinal products for the purpose of indicating that they are the goods of a particular person by virtue of manufacture, selection, certification, dealing with or offering for sale or supply;

"specified publication" means any of the following —

(a) British National Formulary;

(b) British Pharmacopoeia;

(c) European Pharmacopoeia;

(d) Japanese Pharmacopoeia;

(e) Pharmaceutical Codex (British);

(f) US Pharmacopoeia National Formulary.

Particulars to be shown on label

3. Where a medicinal product is a dispensed medicinal product, the container of the medicinal product shall be labelled to show the following particulars —

(a) the name of the person to whom the medicinal product is to be administered;

(b) the name and address of the medical or dental practice, registered pharmacy, hospital or any other institution where the medicinal product is supplied or dispensed and any other identification number or mark;

(c) the date upon which the medicinal product is dispensed;

(d) the direction for use of the medicinal product;

(e) the name of the medicinal product being either the appropriate non-proprietary name or the proprietary designation; and

(f) where the appropriate non-proprietary name is labelled, the appropriate quantitative particulars of the active ingredients of the medicinal product.

Exception for clinical trial

4. Notwithstanding regulation 3, where a medicinal product is for administration in a clinical trial, the container of the medicinal product need not be labelled with the particulars referred to in regulation 3*(e)* and *(f)*.

Certain substances to be labelled

5. (1) This regulation applies where any medicinal product for human consumption or use, containing any substance specified in the first column of Schedule 1, not being a dispensed medicinal product, is sold by retail or supplied in circumstances corresponding to retail sale or is in the possession of any person for the purpose of such sale or supply.

(2) Every container of a product referred to in sub-regulation (1) and, where the container is immediately enclosed in a package, the package shall be labelled with a statement in English declaring the presence of that substance which may describe that substance by a corresponding term specified in the second column of Schedule 1 or any other equivalent term.

Products to carry date stamp

6. Subject to regulation 7, where any medicinal product containing any substance specified in Schedule 2, not being a dispensed medicinal product, is sold or supplied by way of wholesale dealing, or sold by retail or supplied in circumstances corresponding to retail sale, or is in the possession of any person for the purpose of such sale or supply, every container of that product and, where the container is immediately enclosed in a package, every such package shall be labelled to show the words “Use by” or other similar words followed by the expiry date of the medicinal product.

Exception

7. Regulation 6 does not apply to any medicinal product —

(a) containing Ascorbic Acid (Vitamin C) or any of its salts which is for sale as confectionery and which is not or is not to be sold with, accompanied by or having in relation to it, any particulars in writing specifying that product’s curative or remedial function, or the use of that product for such curative or remedial purposes in relation to a disease specified on the container other than coughs, colds or nasal congestion; or

(b) comprising wholly of any of the substances specified in Schedule 2 which is sold or supplied by way of wholesale dealing for use mainly as an ingredient in the preparation of a substance or article which is to be administered to one or more human beings or animals for a medicinal purpose.

Labels, dimensions position etc.

8. (1) All particulars required by these Regulations to be shown by the labelling of any container or package of a medicinal product shall be printed in letters not less than 1.5 millimetres in height and shall be clearly legible and appear conspicuously in a prominent position on the label so as to be easily read by an intending purchaser or user of the medicinal product under normal conditions of purchase or use.

(2) Notwithstanding sub-regulation (1), such statement may be printed in reduced size clearly legible where the container or package of a medicinal product is so small as to prevent the use of wording of the size specified in sub-regulation (1).

(3) Where a container which is in the form of a bubble, blister or other sealed unit is part of a continuous series comprising a sheet or strip of like containers, regulations 5 and 6 are deemed to have been complied with if the particulars referred to in those regulations are displayed at frequent intervals on the sheet or strip of such containers.

(4) Where the package immediately enclosing a container referred to in sub-regulation (3) is itself in the form of a bubble, blister or other sealed unit and is part of a continuous series comprising a sheet or strip of like packages, regulations 5 and 6 are deemed to have been complied with if the particulars referred to in those regulations are displayed at frequent intervals on the sheet or strip of such packages.

(5) Every package immediately enclosing a package to which sub-regulation (4) refers shall, where regulation 5 or 6 is applicable, be labelled to show the particulars referred to in regulation 5 or 6 or both, as the case may be.

(6) Nothing in these Regulations shall prohibit the addition in any language of such matter descriptive of the contents of the container or of any other particulars provided that such addition is not contrary to or in modification of the particulars required by these Regulations to be printed on a label.

Labelling in indelible manner

9. All labelling of containers and packages of medicinal products shall be carried out in an indelible manner.

SCHEDULE 1

(regulation 5)

	Substance	*Term to be used*
1.	Tartrazine	tartrazine (Code E102)
		tartrazine (Code 102)
		tartrazine (Code FD and C Yellow No.5)
2.	Benzoic acid	benzoic acid
		benzoic acid (Code E210)
3.	Sodium benzoate	sodium benzoate
		sodium benzoate (Code E211).

SCHEDULE 2

(regulation 6)

1. Acetylsalicylic Acid (Aspirin) and its salts
2. Alpha Tocopherol (Vitamin E) and its salts
3. Anaesthetic Ether
4. Antibiotics and antifungal agents
5. Antitoxins
6. Ascorbic Acid (Vitamin C) and its salts
7. Blood products
8. Chloral Hydrate
9. Cyanocobalamin (Vitamin B12)
10. Ferrous Salts
11. Glyceryl Trinitrate
12. Insulins
13. Nicotinamide
14. Paracetamol (Acetaminophen)

SCHEDULE 2 — *(continued)*

15. Paraldehyde (Oral and Systemic Preparations)
16. Pyridoxine Hydrochloride (Vitamin B6)
17. Retinol (Vitamin A) and its salts
18. Riboflavine and its salts
19. Sodium Nitrite Injection
20. Sodium Thiosulphate Injection
21. Thiamine/Aneurine (Vitamin B1) and their salts
22. Vaccines.