Medicines (Labelling) Regulations

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MEDICINES ACT
(CHAPTER 176, SECTION 44)

MEDICINES (LABELLING) REGULATIONS

Rg 5

G.N. No. S 255/1986

REVISED EDITION 2000

(31st January 2000)

[31st March 1987]

Citation

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

2. [*Deleted by S 545/2016 wef 01/11/2016*]

Definitions

3. 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;

"Chinese proprietary medicines" shall have the same meaning as in the Medicines (Traditional Medicines, Homoeopathic Medicines and other Substances) (Exemption) Order (O 6);

"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*) European Pharmacopoeia;

(*b*) British Pharmacopoeia;

(*c*) US Pharmacopoeia National Formulary;

(*d*) Pharmaceutical Codex (British); or

(*e*) British National Formulary.

Scope of Regulations

3A. These Regulations do not apply to —

(*a*) Chinese proprietary medicines; and

(*b*) any medicinal product (other than any Chinese proprietary medicine) that is clinical research material as defined in regulation 2 of the Medicines (Medicinal Products as Clinical Research Materials) Regulations 2016 (G.N. No. S 336/2016).

[S 545/2016 wef 01/11/2016]

Particulars to be shown on label

4. 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.

5. [*Deleted by S 545/2016 wef 01/11/2016*]

Certain substances to be labelled

6.—(1) This regulation shall apply where any medicinal product for human consumption or use, containing any substance specified in the first column of the First Schedule, 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 paragraph (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 the First Schedule or any other equivalent term.

Products to carry date stamp