Trade descriptions

19.—(1) For the purposes of section 18(1) of the Act, the presentation of a therapeutic product must comply with all of the following requirements:

(*a*) a trade description which is false or misleading must not be applied to the therapeutic product;

(*b*) a trade description which explicitly or implicitly suggests that the supply or use of the therapeutic product is promoted or endorsed by the Authority, the Ministry of Health or the Health Promotion Board must not be applied to the therapeutic product.

(2) For the purposes of paragraph (1)(*a*), a trade description is false or misleading if —

(*a*) it contains any false statement or information concerning the therapeutic product; or

(*b*) it is likely to create an erroneous impression regarding the formulation, composition, quality, safety, efficacy or uses of the therapeutic product.

(3) For the purposes of paragraph (1), a person applies a trade description to a therapeutic product if the person —

(*a*) affixes or annexes the trade description to, or in any manner marks it on or incorporates it in —

(i) the therapeutic product; or

(ii) any thing in or on the therapeutic product or with which the therapeutic product is supplied;

(*b*) places the therapeutic product in, on or with any thing which the trade description has been affixed or annexed to, marked on or incorporated in; or

(*c*) makes any oral or written statement of the trade description, or uses the trade description in any other manner, which is likely to be understood as referring to the therapeutic product.

(4) A person supplying a therapeutic product is taken to have applied a trade description to the therapeutic product if —

(*a*) the therapeutic product is supplied pursuant to a request in which the trade description is used; and

(*b*) it is reasonable in the circumstances to infer that any therapeutic product so

supplied will correspond to that trade description.

Information to be provided with therapeutic products

20.—(1) In addition to regulation 19, a therapeutic product must, for the purposes of section 18(1) of the Act, be accompanied by all of the following information, where applicable, when it is supplied:

(*a*) the name of the therapeutic product, being the proprietary name and the appropriate non-proprietary name;

(*b*) the appropriate quantitative particulars of any active ingredient of the therapeutic product;

(*c*) an appropriate control number, such as a serial number, batch number or lot number;

(*d*) the expiry date of the therapeutic product;

(*e*) where the therapeutic product is registered, the registration number assigned to the registered therapeutic product by the Authority.

(2) Where a therapeutic product contains any substance specified in the first column of the Fourth Schedule, the therapeutic product must be labelled with a statement declaring the presence of that substance, and that substance may be described by a corresponding term specified in the second column of that Schedule.

(3) Where a therapeutic product contains any substance specified in the first column of the Fifth Schedule, the therapeutic product must be labelled with the caution set out in the second column of that Schedule.

(4) Where a therapeutic product is contained in a container, which is 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 containers, paragraph (2) or (3), as the case may be, is taken to have been complied with if the statement mentioned in paragraph (2) or the caution mentioned in paragraph (3) is printed or displayed or otherwise marked in a prominent position at frequent intervals on the sheet or strip of the container.

(5) All information accompanying the therapeutic product mentioned in paragraph (1), including the statement mentioned in paragraph (2) and the caution mentioned in paragraph (3) —

(*a*) must be provided in English; and

(*b*) must be legible and indelible.

FOURTH SCHEDULE

Regulation 20(2)

	First column *Substance*	*Second column* *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)

FIFTH SCHEDULE

Regulation 20(3)

CAUTIONARY INFORMATION TO BE LABELLED ON THERAPEUTIC PRODUCTS

	First column *Therapeutic product*	*Second column* *Cautionary information*
1.	Therapeutic product containing aspirin or acetylsalicylic acid for oral administration	Caution: Not to be given to persons below 16 years of age except under the direction of a doctor.
2.	Therapeutic product containing any of the following substances for oral administration: (*a*) Diphenoxylate (*b*) Loperamide (*c*) The following anti-histamine substances: Antazoline Azatadine Bamipine Bromodiphenhydramine	Caution: This may cause drowsiness. If affected, do not drive or operate machinery.

Bromopheniramine

Buclizine

Carbinoxamine

Chlorcyclizine

Chlorpheniramine

Cinnarizine

Clemastine

Clemizole

Cyclizine

Cyproheptadine

Dexchlorpheniramine

Dimethpyrindene

Diphenhydramine

Diphenylpyraline

Doxylamine

Embramine

Flunarizine

Homochlorcyclizine

Isothipendyl

Levocabastine

Mebhydrolin

Meclastine

Meclozine

Mepyramine

Mequitazine

Methdilazine

Oxatomide

Oxomemazine

Phenindamine

Pheniramine

Phenyltoloxamine

Promethazine

Pyrathiazine

Pyrrobutamine

Thenalidine

Thenyldiamine

Thiazinamium

Tolpropamine

Tripelennamine

Triprolidine