STATUTORY INSTRUMENTS

1978 No. 41

The Medicines (Labelling and Advertising to the Public) Regulations 1978

Exceptions for labels and leaflets

9.—(1) The prohibitions, restrictions and requirements imposed by any provision of these regulations do not apply to any labelled container or package of a medicinal product or any other substance or article or any leaflet supplied with such product where that product is prepared or dispensed with a view to administration to a person in accordance with the prescription of a doctor or dentist.

(2) The prohibition imposed by regulation 4(1) of these regulations does not apply to a labelled container or package of a medicinal product or to a leaflet supplied, or intended to be supplied with a medicinal product which—

(a) is a herbal remedy, not being a herbal remedy of a description, or falling within a class, specified in any order made under section 56(3) of the Act (exceptions in respect of herbal remedies), or

(b) consists of one or more of the dilutions of unit preparations of any substance having been diluted to at least one part of a million (6x),

(c) is a medicinal product prepared and dispensed by a pharmacist in accordance with his own judgment for the treatment required by the person to whom that medicinal product is to be administered if—

(i) he prepares or dispenses that medicinal product at the request of that person, and

(ii) that person is present in the pharmacy in which that medicinal product is so prepared at the time of making such request,

and the conditions specified in paragraph (3) below are satisfied.

(3) The conditions referred to in paragraph (2) above are—

(a) that the labelled container and package of, and any leaflet supplied with, a medicinal product to which that paragraph applies shall not include any word or phrase specified in Schedule 4 to these regulations except in so far as the inclusion of any such word or phrase is necessary to explain the contra-indications or precautions or the action to be taken in the event of over-dosage of the medicinal product;

(b) that every container and package of such medicinal product shall be labelled to show, and every leaflet supplied with such medicinal product shall include, such of the phrases and particulars specified in paragraph 1 of Schedule 5 to these regulations as may be appropriate in any particular case and the warning specified in paragraph 2 of that Schedule, which shall be completed in the manner specified in paragraph 3 of that Schedule;

(c) that the labelled container and package of, and any leaflet supplied, or intended to be supplied with, the medicinal product shall not contain any reference to any disease or purpose in respect of which the issue of advertisements is prohibited by the provisions of these regulations, other than the name of any disease which is required to be shown

on containers and packages and included in leaflets in accordance with the requirements imposed by sub-paragraph (b) above and Schedule 5 to these regulations;

(d) that the warning required to be shown on containers and packages and leaflets in accordance with sub-paragraph (b) above shall be within a rectangle within which there shall be no other matter of any kind.

(4) In this regulation "unit preparation" means a preparation, including a mother tincture, prepared by a process of solution, extraction or trituration with a view to being further diluted tenfold, or serially in multiple powers of ten, in an inert diluent, and then used either in this diluted form or, where applicable, by impregnating tablets, granules, powders or other inert substances for the purpose of being administered to human beings.