STATUTORY INSTRUMENTS

1994 No. 1932

The Medicines (Advertising) Regulations 1994

PART I

GENERAL

Citation and commencement

1. These Regulations may be cited as the Medicines (Advertising) Regulations 1994 and shall come into force on 9th August 1994.

Interpretation

2.—(1) In these Regulations—

"the Act" means the Medicines Act 1968;

"abbreviated advertisement" means an advertisement, other than a loose insert, which does not exceed in size an area of 420 square centimetres, in a publication sent or delivered wholly or mainly to persons qualified to prescribe or supply relevant medicinal products;

"common name" in relation to a relevant medicinal product means the international non-proprietary name, or, if one does not exist, the usual common name;

"essential information compatible with the summary of product characteristics" means essential information compatible—

(a) with the summary of product characteristics, if there is one, or

(b) if there is no summary of product characteristics, with the data sheet,

and "essential information" has the meaning it bears in Council Directive 92/28/EEC(**1**);

"medicinal product for supply by prescription only" means a medicinal product of a description or falling within a class specified in any order made under section 58 of the Act(**2**);

"medicinal product on a general sale list" means a medicinal product of a description or falling within a class specified in any order made under section 51(1) of the Act;

"name" in relation to a relevant medicinal product means the name given to the product which may be either an invented name or a common or scientific name, together with a trade mark or the name of the person responsible for marketing the product;

"pharmacy medicinal product" means a medicinal product which is neither a medicinal product for supply by prescription only nor a medicinal product on a general sale list;

"promotional aid" means a non-monetary gift made for a promotional purpose by a commercially interested party;

"reference material" includes entries which are in the form of, and limited to, a brief description of a medicinal product, its uses and any relevant contra-indications and warnings, appearing

(**1**) OJNo. L113, 30.4.1992, p.13.
(**2**) Section 58 was amended by the Medicinal Products: Prescription by Nurses etc Act 1992 (c. 28), as from a day to be appointed.

without charge in a publication consisting wholly or mainly of such entries where the publication is sent or delivered to persons qualified to prescribe or supply relevant medicinal products by a person who is not a commercially interested party;

"registered homoeopathic medicinal product" means a homoeopathic medicinal product(**3**)to which Council Directive 92/73/EEC(**4**)applies which is marketed in the United Kingdom under a certificate of registration(**5**)in accordance with the provisions of the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994(**6**);

"relevant medicinal product" means—

(a) a medicinal product for human use to which Chapters II to V of the 1965 Directive(**7**)apply,

(b) a substance or article for human use—

(i) to which Chapters II to V of the 1965 Directive apply, and

(ii) specified in an order made under section 104 or 105 of the Act or in regulations made under section 2(2) of the European Communities Act 1972, which direct that Part VI or any section of that Part of the Act has effect in relation to such substance or article as that Part or section has effect in relation to medicinal products within the meaning of the Act, or

(c) a registered homoeopathic medicinal product,

but does not include a homoeopathic medicinal product in respect of which there is in force a product licence being a licence of right;

"summary of product characteristics" means the information required to accompany any application for a product licence by virtue of article 4a of the 1965 Directive which was inserted by article 1(2) of Council Directive 83/570/EEC(**8**)and amended by article 1(1) and (4) of Council Directive 89/341/EEC(**9**);

and expressions used in these Regulations which are used in any provision of the Act have, subject to paragraph (2) and unless the context requires otherwise, the meaning which they bear in the Act.

(2) For the purposes of these Regulations, "advertisement" has the meaning assigned to it by section 92 of the Act, except that, in relation to a relevant medicinal product—

(a) provided that it makes no product claim, reference material, a factual, informative statement or announcement, a trade catalogue or a price list shall not be taken to be an advertisement, and

(b) an advertisement includes a representation,

and for the purposes of this paragraph, "representation" has the meaning assigned to it by section 92 of the Act, except that it does not include the making of a factual, informative statement or announcement which includes no product claim.

(3) In these Regulations, unless the context requires otherwise, a reference to a regulation, Part or Schedule is to that regulation in, Part of or Schedule to, these Regulations and any reference in a regulation or Schedule to a numbered paragraph is to the paragraph of that regulation or Schedule bearing that number.

(**3**) The definition of homoeopathic medicinal product was inserted into section 7 of the Act by regulation 3(4) of S.I.1994/276.
(**4**) OJ No. L297, 13.10.1992, p.8.
(**5**) The definition of certificate of registration was inserted into section 7 of the Act by regulation 3(4) of S.I. 1994/276.
(**6**) S.I. 1994/105, amended by S.I. 1994/899.
(**7**) The definition of the 1965 Directive in section 132(1) of the Act was amended by regulation 9 of S.I. 1994/276.
(**8**) OJ No. L332, 28.11.1983, p.1.
(**9**) OJ No. L142, 25.5.1989, p.11.