STATUTORY INSTRUMENTS

2005 No. 768

MEDICINES

The Medicines for Human Use (Marketing Authorisations Etc.) Amendment Regulations 2005

Made - - - -	*16th March 2005*
Laid before Parliament	*17th March 2005*
Coming into force - -	*7th April 2005*

The Secretary of State for Health, being a Minister designated(**1**) for the purposes of section 2(2) of the European Communities Act 1972(**2**) in relation to medicinal products, in exercise of the powers conferred on him by the said section 2(2), hereby makes the following Regulations:

Citation, commencement and interpretation

1.—(1) These Regulations may be cited as the Medicines for Human Use (Marketing Authorisations Etc.) Amendment Regulations 2005 and shall come into force on 7th April 2005.

(2) In these Regulations, "the principal Regulations" means the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994(**3**).

Amendment of regulation 1 of the principal Regulations

2. In regulation 1 of the principal Regulations (citation, commencement and extent)—

(a) after the definition of "the EMEA"(**4**), insert the following definition—

> ""first level nurse" means a person registered in Sub-Part 1 of the Nurses' Part of the professional register;";

(b) after the definition of "parallel import license", insert the following definitions—

> ""professional register" means the register maintained by the Nursing and Midwifery Council under article 5 of the Nursing and Midwifery Order 2001(**5**);
>
> "registered midwife" means a person registered in the Midwives' Part of the professional register;";

(**1**) S.I.1972/1811.
(**2**) 1972 c. 68.
(**3**) S.I. 1994/3144; relevant amending instruments are S.I. 2002/236 and 2004/865, 1016 and1031.
(**4**) The definition of "EMEA" was substituted by S.I. 2004/3224.
(**5**) S.I. 2002/253.

(c) after the definition of "relevant medicinal product"(**6**), insert the following definitions—

""relevant register" means—

(a) in relation to a first level nurse or registered midwife, the professional register;

(b) in relation to a pharmacist, the register maintained in pursuance of section 2(1) of the Pharmacy Act 1954(**7**) or the register maintained in pursuance of Articles 6 and 9 of the Pharmacy (Northern Ireland) Order 1976(**8**); and

(c) in relation to a person whose name is registered in the part of the register maintained by the Health Professions Council in pursuance of article 5 of the Health Professions Order 2001(**9**) relating to—

(i) chiropodists and podiatrists;

(ii) physiotherapists;

(iii) radiographers: diagnostic or therapeutic,

that register;

"supplementary prescriber" means—

(a) a first level nurse,

(b) a pharmacist,

(c) a registered midwife, or

(d) a person whose name is registered in the part of the register maintained by the Health Professions Council in pursuance of article 5 of the Health Professions Order 2001relating to—

(i) chiropodists and podiatrists;

(ii) physiotherapists;

(iii) radiographers: diagnostic or therapeutic,

against whose name is recorded in the relevant register, an annotation or entry signifying that he is qualified to order drugs, medicines and appliances as a supplementary prescriber.".

Amendment of Schedule 1 to the principal Regulations

3. In Schedule 1 to the principal Regulations (exemptions and exceptions from the provisions of regulation 3)—

(a) in paragraph 1, for " or dentist", substitute ", dentist or supplementary prescriber"

(b) in paragraph 2—

(i) in sub-paragraph (a), for "or dentist", substitute ", dentist or supplementary prescriber"; and

(ii) in sub-paragraph (c), for "or dentist", substitute ", dentist or supplementary prescriber".

(**6**) The definition of "relevant medicinal product" was substituted by S.I. 2002/236.
(**7**) 1954. c. 61.
(**8**) S.I. 1976/1213 (N.I. 22).
(**9**) S.I. 2002/254.

Signed by authority of the Secretary of State for Health

Warner
Parliamentary Under Secretary of State,
16th March 2005 Department of Health

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations further amend the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994 ("the principal Regulations"). The principal Regulations implement certain provisions of Directive 2001/83/EC of the European Parliament and of the Council on the community code for medicinal products for human use ("the 2001 Directive")(**10**). In particular, the principal Regulations implement the provisions of the 2001 Directive which relate to marketing authorisations. Schedule 1 of the principal Regulations, which this instrument amends, exercises the derogation in article 5 of the 2001 Directive.

Regulation 2 inserts a definition of "supplementary prescriber" into the principal Regulations.

Regulation 3 amends paragraphs 1 and 2 of Schedule 1 to the principal Regulations. Schedule 1 contains exceptions to the requirement that no relevant medicinal product may be placed on the market or distributed by way of wholesale dealing unless a marketing authorisation for that product has been granted. The exemption in paragraphs 1 and 2 provide that no marketing authorisation is required in respect of the sale or supply of a relevant medicinal product in response to a bona fide unsolicited order formulated in accordance with the specification of a doctor or dentist and for use by his individual patients on his personal responsibility. This amendment provides that a relevant medicinal product may also be sold or supplied in such circumstances where the medicinal product is formulated in accordance with the order of a supplementary prescriber.

A Regulatory Impact Assessment in relation to these Regulations has been placed in the libraries of both Houses of Parliament and copies may be obtained from the Department of Health, Medicines and Healthcare products Regulatory Agency, Information Centre, Room 10-202 Market Towers, 1 Nine Elms Lane, London SW8 5NQ.

(**10**) OJNo. L311, 28.11.2001, p.34.