
STATUTORY INSTRUMENTS

2000 No. 292

MEDICINES

**The Medicines for Human Use (Marketing
Authorisations Etc.) Amendment Regulations 2000**

<i>Made</i>	- - - -	<i>8th February 2000</i>
<i>Laid before Parliament</i>		<i>9th February 2000</i>
<i>Coming into force</i>		
<i>except for regulation 4(2)</i>		<i>1st March 2000</i>
<i>regulation 4(2)</i>		<i>1st March 2001</i>

The Secretary of State and the Minister of Health, Social Services and Public Safety, being Ministers designated for the purposes of section 2(2) of the European Communities Act 1972⁽¹⁾ in relation to medicinal products⁽²⁾, acting jointly, in exercise of the powers conferred by the said section 2(2) and of all other powers enabling them in that behalf, hereby make 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 2000 and—

- (a) except for regulation 4(2), shall come into force on 1st March 2000; and
- (b) regulation 4(2) shall come into force on 1st March 2001.

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

Amendment of regulation 1(2) of the principal Regulations

2. In the definition of “the relevant Community provisions” in regulation 1(2) of the principal Regulations (interpretation)—

(1) 1972 c. 68.
(2) S.I. 1972/1811; as respects the reference to any Minister of the Government of Northern Ireland in the last entry in column 1 of the Schedule to this Order, see paragraph 11(1)(a) of Schedule 12 to the Northern Ireland Act 1998 (c. 47) for the construction of references in existing enactments to an unspecified Minister of Northern Ireland.
(3) S.I. 1994/3144; amended by S.I. 1998/3105.

- (a) in the list of Community provisions, at the end of the entry “Council Directive [75/318/EEC](#)(4)” there shall be added “as last amended by Commission Directive [1999/83/EC](#)(5)”; and
- (b) for the words from “as they have” to “into force” there shall be substituted the words “but the amendments to the Annex of Council Directive [75/318/EEC](#) in Commission Directive [1999/82/EC](#)(6) shall only apply as respects new applications for marketing authorizations from 1st July 2000 and as respects all marketing authorizations from 1st March 2001”.

Insertion of regulation 3A into the principal Regulations

3. After regulation 3 of the principal Regulations (marketing authorizations for relevant medicinal products) there shall be inserted the following regulation—

“Borderline products

3A.—(1) Where the licensing authority are of the opinion that a product without a marketing authorization is a relevant medicinal product, they may, by a notice in writing (referred to in this regulation as a “provisional determination notice”) served on any person who has placed or who in the opinion of the licensing authority may place the product on the market—

- (a) inform him that they are minded to determine that the product is a relevant medicinal product (referred to in this regulation as “the provisional determination”) and of the reasons why they are so minded; and
- (b) advise him that if he disagrees with the provisional determination, he may request that the licensing authority review their provisional determination, provided that within four weeks of the date on which the provisional determination notice was served on him (referred to in this regulation as “the date of the provisional determination”) he makes that request, and
 - (i) within such period (being not less than six weeks from the date of the provisional determination) as may be specified in the provisional determination notice, he furnishes the licensing authority with written representations explaining why he considers that the product is not a relevant medicinal product, or
 - (ii) within four weeks of the date of the provisional determination, he informs the licensing authority in writing that he wishes to make oral representations to a review panel, appointed by the licensing authority, explaining why he considers that the product is not a relevant medicinal product.

(2) Where the licensing authority have been informed, pursuant to paragraph (1)(b) (ii), that a person wishes to make oral representations to a review panel, they shall, after consultation with that person, set a date for the oral hearing (at which the licensing authority may also make oral representations to the panel) and, subject to paragraph (3), that date shall be the date fixed for the oral hearing.

(3) Where the licensing authority consider that, because of either exceptional circumstances or the nature and complexity of the issues, additional time is needed—

(4) OJNo. L 147, 9.6.1975, p. 1. This Directive has been amended by Council Directive [95/319/EEC](#) (OJ No. L 147, 9.6.1975, p. 13), Council Directive [83/570/EEC](#) (OJ No. L332, 28.11.1983, p. 1), Council Directive [87/19/EEC](#) (OJ No. L 15, 17.1.1987, p. 31), Council Directive [89/341/EEC](#) (OJ No. L 142, 25.5.1989, p. 11) Commission Directive [91/507/EEC](#) (OJ No. L270, 26.9.1991, p. 32), Council Directive [93/39/EEC](#) (OJ No. L214, 24.8.93, p. 22), Commission Directive [1999/82/EC](#) (OJ No. L 243, 15.9.1999, p. 7) and Commission Directive [1999/83/EC](#) (OJ No. L243, 15.9.1999, p. 7).

(5) For the OJ reference for this Directive and the other Directives amending Council Directive [75/318/EEC](#), see the previous footnote entry.

(6) *ibid.*

- (a) for the preparation of written representations in a case where the licensing authority have not been informed, pursuant to paragraph (1)(b)(ii), that the person on whom the provisional determination notice was served wishes to make oral representations, the licensing authority may alter the period specified in the notice within which written representations are to be furnished to a different period, and then that different period shall be the period within which the written representations are to be furnished;
- (b) for preparation for the oral hearing, they may alter the date set for the hearing to a different date, and then that different date shall be the date fixed for the oral hearing,

and they shall inform the person on whom the relevant provisional determination notice was served of the alteration and the reasons for it.

- (4) Where a person on whom a provisional determination notice has been served—
 - (a) has not requested that the licensing authority review their provisional determination within four weeks of the date of the provisional determination; or
 - (b) has made such a request but has not availed himself of the opportunities afforded to him under the procedure set out in this regulation to make representations explaining why he considers that the product in respect of which the provisional determination has been made is not a relevant medicinal product,

the licensing authority shall, after further consideration of the matter, determine whether or not the product is a relevant medicinal product and shall inform that person in writing of their determination and their reasons for it.

- (5) If a person on whom a provisional determination notice was served—
 - (a) has made written representations to the licensing authority pursuant to paragraph (1)(b)(i), read with paragraph (3)(a), the licensing authority shall—
 - (i) put those written representations before a review panel, appointed by the licensing authority, together with any written representations which the licensing authority may make to the panel on the matter, and
 - (ii) after further consideration of the matter, and in particular after having considered the advice of the review panel arising out of those representations and any other evidence considered by the review panel, determine whether or not the product is a relevant medicinal product;
 - (b) has made oral representations to a review panel at an oral hearing arranged pursuant to paragraph (2), read with paragraph (3)(b), the licensing authority shall, after further consideration of the matter and in particular after having considered the advice of the review panel arising out of—
 - (i) the oral representations made and any other evidence submitted to the panel at the hearing by that person,
 - (ii) any oral representations made and any other evidence submitted to the panel at the hearing by the licensing authority, and
 - (iii) any other evidence considered by the review panel,determine whether or not the product is a relevant medicinal product,

and shall inform that person in writing of their determination and their reasons for it, and if the licensing authority make a determination which is contrary to the advice of the review panel, they shall also give their reasons for disagreeing with the advice of the review panel.

(6) In respect of any product which the licensing authority determine, in accordance with paragraph (4) or (5), to be a relevant medicinal product, the licensing authority may,

by a notice in writing served on any person who has placed or who in the opinion of the licensing authority may place the product on the market, require that he shall—

- (a) stop marketing the product from a date specified in the notice; or
- (b) not place the product on the market,

unless or until a marketing authorization is granted in respect of that product.

(7) Nothing in this regulation precludes a determination by the licensing authority that a product is a relevant medicinal product otherwise than in accordance with this regulation in appropriate circumstances.”.

Amendment of Schedule 3 to the principal Regulations

4.—(1) After paragraph 1 of Schedule 3 to the principal Regulations (offences, penalties etc.) there shall be inserted the following paragraph—

“**1A.** In respect of any product which is a relevant medicinal product, where, following a determination under regulation 3A(4) or (5), the licensing authority serve a notice in respect of that product on any person under regulation 3A(6) requiring him—

- (a) to stop marketing the product from a date specified in the notice unless or until a marketing authorization is granted in respect of that product, if after the date specified—
 - (i) he places that product on the market, or
 - (ii) in the course of a business carried on by him, he sells, supplies to a member of the public or procures for sale or for supply to a member of the public that product,

without a marketing authorization having been granted in respect of that product, he shall be guilty of an offence;

- (b) not to place the product on the market unless or until a marketing authorization is granted in respect of that product, if he thereafter places the product on the market without a marketing authorization having been granted in respect of that product, he shall be guilty of an offence.”.

(2) In paragraph 6(c) of Schedule 3 to the principal Regulations (offences, penalties etc.—obligations of holders of marketing authorizations), after the words “those Articles” there shall be added the words “or paragraph C.a of Part 2 of the Annex to Council Directive [75/318/EEC](#)”.

Amendment of Schedule 5 to the principal Regulations

5. In paragraph 5(1) of Schedule 5 to the principal Regulations(7) (labels—relevant medicinal products on a general sale list), in paragraphs (f)(i) and (g)(i), for the word “case”, at each place where it occurs, there shall be substituted the word “event”.

Signed by authority of the Secretary of State for Health

8th February 2000

Hunt
Parliamentary Under Secretary of State
Department of Health

3rd February 2000

Bairbre de Brún
Minister of Health, Social Services and Public
Safety

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations make amendments to the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994 (“the principal Regulations”), which implemented in respect of the United Kingdom a range of European Community measures relating to the marketing of medicinal products for human use.

Regulation 2 amends the definition of “the relevant Community provisions” in the principal Regulations, updating the reference to Council Directive [75/318/EEC](#) on the approximation of the laws of member States relating to analytical, pharmacotoxicological and clinical standards and protocols in respect of the testing of medicinal products. As a result, it now refers to that Directive as amended by Commission Directives [1999/82/EC](#) and [1999/83/EC](#). Commission Directive [1999/82/EC](#) relates to compliance with the European Commission’s “Note for Guidance on Minimising the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Medicinal Products” which is applied to new applications for marketing authorizations for medicinal products from 1st July 2000 and to all marketing authorizations from 1st March 2001. The principal Regulations are also amended so that, from the latter date, a holder of a marketing authorization who fails to introduce any changes or make any amendments that may be required to demonstrate compliance with that Guideline may be guilty of an offence (regulation 4(2)).

Regulation 3 inserts a new regulation 3A into the principal Regulations. It contains a new statutory procedure for determinations by the licensing authority as defined in the Medicines Act 1968(8), as to whether or not a product is a “relevant medicinal product”. The procedure allows for representations to be made against provisional determinations, and for those representations to be considered by a review panel appointed by the licensing authority. Once a final determination has been made, the licensing authority may serve a notice requiring a person not to place a product determined to be a relevant medicinal product on the market, or to stop marketing it from a date specified, unless or until a marketing authorization has been granted in respect of the product. A new provision is inserted into Schedule 3 of the principal Regulations making breach of such a notice an offence in respect of relevant medicinal products (regulation 4(1)).

Regulation 5 makes a minor amendment to the special warnings which must be included on the packaging of medicinal products containing paracetamol on the general sale list, other than products prepared or dispensed in accordance with a prescription given by a medical practitioner.

(8) [1968 c. 67](#); see section 6 of that Act.