STATUTORY INSTRUMENTS

1998 No. 3105

MEDICINES

The Medicines for Human Use (Marketing Authorisation Etc.) Amendment Regulations 1998

Made - - - -	*10th December 1998*
Laid before Parliament	*11th December 1998*
Coming into force - -	*1st January 1999*

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

Citation, commencement and interpretation

1.—(1) These Regulations may be cited as the Medicines for Human Use (Marketing Authorisation Etc.) Amendment Regulations 1998 and shall come into force on 1st January 1999.

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

Amendment of regulation 11 of the principal Regulations

2. In regulation 11 of the principal Regulations (other Schedules to have effect), after the words "Schedule 5 (labels),", there shall be inserted the words "Schedule 5A (package leaflets),".

Amendment of Schedule 5 to the principal Regulations

3.—(1) After paragraph 5(1)(e) of Schedule 5 to the principal Regulations (labels—relevant medicinal products on a general sale list), there shall be added the following—

"(f) if the product contains paracetamol, unless it is wholly or mainly intended for children who are twelve years old or younger, the words "Do not take with any other paracetamol —con taining products", and

(**1**) 1972 c. 68.
(**2**) S.I.1972/1811.
(**3**) S.I. 1994/3144.

(i) if a package leaflet accompanying the product displays the words set out in quotation marks in paragraph 1 of Schedule 5A, the words "Immediate medical advice should be sought in the case of an overdose, even if you feel well", or

(ii) if no package leaflet accompanies the product or the package leaflet does not display the words in paragraph 1 of Schedule 5A, the words "Immediate medical advice should be sought in the event of an overdose, even if you feel well, because of the risk of delayed, serious liver damage";

(g) if the product contains paracetamol and is wholly or mainly intended for children who are twelve years old or younger, the words "Do not give with any other paracetamol—containing products"; and

(i) if a package leaflet accompanying the product displays the words set out in quotation marks in paragraph 2 of Schedule 5A, the words "Immediate medical advice should be sought in the case of an overdose, even if the child seems well", or

(ii) if no package leaflet accompanies the product or the package leaflet does not display the words in paragraph 2 of Schedule 5A, the words "Immediate medical advice should be sought in the event of an overdose, even if the child seems well, because of the risk of delayed, serious liver damage"."

(2) In paragraph 5(2)(b) of Schedule 5 to the principal Regulations (labels—relevant medicinal products on a general sale list), after the words "of those sub-paragraphs" there shall be inserted the words "or sub-paragraph (1)(f) or (g)".

Insertion of Schedule 5A to the principal Regulations

4. After Schedule 5 to the principal Regulations (labels), there shall be inserted the following Schedule—

"SCHEDULE 5A Regulation 11

LEAFLETS

1. Where in accordance with the relevant Community provisions a package leaflet is included in the packaging of a relevant medicinal product containing paracetamol, unless the product is wholly or mainly intended for children who are twelve years old or younger the leaflet shall display the words "Immediate medical advice should be sought in the event of an overdose, even if you feel well, because of the risk of delayed, serious liver damage".

2. Where in accordance with the relevant Community provisions a package leaflet is included in the packaging of a relevant medicinal product containing paracetamol and the product is wholly or mainly intended for children who are twelve years old or younger, the leaflet shall display the words "Immediate medical advice should be sought in the event of an overdose, even if the child seems well, because of the risk of delayed, serious liver damage"."

Amendment of Schedule 3 to the principal Regulations

5.—(1) In paragraph 11 of Schedule 3 to the principal Regulations, after the words "or of Schedule 5", there shall be inserted the words "or 5A".

(2) In paragraph 12 of Schedule 3 to the principal Regulations, after the words "or of Schedule 5", there shall be inserted the words "or 5A".

Signed by authority of the Secretary of State for Health

Hayman
Parliamentary Under Secretary of State,
Department of Health

10th December 1998

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the Medicines for Human Use (Marketing Authorisation Etc.) Regulations 1994 ("the principal Regulations") to make further provision implementing Council Directive 92/27/EEC (O.J. No. L113 of 30.4.1992) ("the Directive") by requring necessary special warnings to be included on the packaging of relevant medicinal products containing paracetamol, and in package leaflets accompanying those products.

The new paragraph 5(1)(f) of Schedule 5 to the principal Regulations specifies the new warnings which must appear on the packaging of paracetamol products for adult use. The new paragraph 5(1)(g) specifies similar warnings in respect of products for paediatric use. Paragraph 5(2) of Schedule 5 to the principal Regulations is amended so that the required label warnigns must appear prominently and in a rectangle (regulation 3).

Paragraph 1 of the new Schedule 5A to the principal Regulations specifies the new warning which must appear in any package leaflet included in accordance with the Directive in the packaging of a paracetamol product for adult use, and paragraph 2 of the Schedule specifies the warning which must appear in any package leaflet included in accordance with the Directive in the packaging of a paracetamol product for paediatric use (regulation 4).

Consequential amendments are made to paragraphs 11 and 12 of Schedule 3 to the principal Regulations, making breaches of the new requirements offences (regulation 5).

A Regulatory Appraisal in relation to these Regulations has been placed in the libraries of both Houses of Parliament, and copies can be obtained from the Medicines Control Agency, Room 1207, Market Towers, 1 Nine Elms Lane, London SW8 5NQ.