2003 No. 1618

MEDICINES

The Medicines for Human Use (Marketing Authorisations Etc.) Amendment Regulations 2003

Made - - - - -	*20th June 2003*
Laid before Parliament	*27th June 2003*
Coming into force - -	*1st October 2003*

The Secretary of State, being a Minister designated for the purposes of section 2(2) of the European Communities Act 1972(**a**) in relation to medicinal products(**b**), 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 Authorisations Etc.) Amendment Regulations 2003 and shall come into force on 1st October 2003.

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

Amendment of Schedule 5 to the principal Regulations

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

"(h) if the product contains aspirin or aloxiprin, the words "Do not give to children aged under 16 years, unless on the advice of a doctor."."

Amendment of Schedule 5A to the principal Regulations

3. After paragraph 2 of Schedule 5A to the principal Regulations (leaflets), there shall be added the following paragraph—

(**a**) 1972 c.68.
(**b**) S.I. 1072/1811.
(**c**) S.I. 1994/3144; the relevant amending instruments are S.I. 1998/3105 and 2000/292.

"**3.** Where in accordance with the relevant Community provisions a package leaflet is included in the packaging of a relevant medicinal product containing aspirin or aloxiprin, the leaflet shall display the words "There is a possible association between aspirin and Reye's syndrome when given to children. Reye's syndrome is a very rare disease, which can be fatal. For this reason aspirin should not be given to children aged under 16 years, unless on the advice of a doctor."."

Signed by authority of the Secretary of State for Health

Warner
Parliamentary Under Secretary of State
Department of Health

20th June 2003

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994 ("the principal Regulations") which implement Council Directive 2001/83/EEC (O.J. No. L311 of 28.11.2001) by requiring necessary special warnings to be included on the packaging of relevant medicinal products containing aspirin or aloxiprin, and in package leaflets accompanying those products.

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

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