STATUTORY INSTRUMENTS

2009 No. 1164

MEDICINES

The Medicines for Human Use (Miscellaneous Amendments) Regulations 2009

Made - - - -	*6th May 2009*
Laid before Parliament	*7th May 2009*
Coming into force - -	*8th May 2009*

The Secretary of State makes the following Regulations in exercise of the powers conferred by section 2(2) of the European Communities Act 1972 [M1]. He is designated for the purposes of that section in relation to medicinal products [M2].

Marginal Citations

M1 1972 c.68; section 2(2) was amended by the Legislative and Regulatory Reform Act 2006 (c.51), **section 27(1)(a)**.

M2 S.I.1972/1811.

Citation and commencement

1. These Regulations may be cited as the Medicines for Human Use (Miscellaneous Amendments) Regulations 2009 and shall come into force on 8th May 2009.

Amendment of Schedule 5 to the Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994

2. After paragraph 8 of Schedule 5 to the Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994 (labels) [M3] insert the following paragraph—

"**9.**—(1) In relation to a relevant medicinal product to which sub-paragraph (2) applies—

(a) paragraphs 1 to 7 do not apply; and

(b) the container of that product shall be labelled to show—

(i) the name of the person to whom the relevant medicinal product is to be administered,

(ii) the date on which the relevant medicinal product is dispensed, and

(iii) the necessary and usual instructions for proper use.

(2) This sub-paragraph applies to a relevant medicinal product which is—

(a) an antiviral medicine in the form of a solution which is to be used for the treatment of a child under the age of one year; and

(b) sold or supplied for the purpose of treating a disease which is—

(i) a serious risk to human health or potentially a serious risk to human health; and

(ii) which is pandemic or is imminently pandemic.".

Marginal Citations

M3 S.I. 1994/3144; Schedule 5 was amended by S.I. 1998/3105, **S.I**. 2000/292, S.I. 2002/236, **S.I**. 2002/542 and S.I. 2003/1618.

Amendment of regulation 30 of the Medicines for Human Use (Clinical Trials) Regulations 2004

3. For paragraph 2 of regulation 30 of the Medicines for Human Use (Clinical Trials) Regulations 2004 (urgent safety measures) [M4], substitute the following paragraphs—

"(2) If measures are taken pursuant to paragraph (1), the sponsor shall—

(a) where paragraph (3) applies, as soon as possible; and

(b) in any other case, immediately, and in any event no later than 3 days from the date the measures are taken,

give written notice to the licensing authority and the relevant ethics committee of the measures taken and the circumstances giving rise to those measures.

(3) This paragraph applies for any period during which a disease—

(a) is pandemic; and

(b) is a serious risk to human health or potentially a serious risk to human health.".

Marginal Citations

M4 S.I. 2004/1031.

Amendment of regulation 8 of the Medicines for Human Use (Manufacturing, Wholesale Dealing and Miscellaneous Amendments) Regulations 2005

4. For paragraph (3) of regulation 8 of the Medicines for Human Use (Manufacturing, Wholesale Dealing and Miscellaneous Amendments) Regulations 2005 (requirement that holders of wholesale dealer's licences comply with certain obligations) [M5], substitute the following paragraph—

"(3) The restriction in paragraph (2) shall not apply to—

(a) the sale or offer for sale of any exempt relevant medicinal product;

(b) the export to an EEA State, or supply for the purposes of such export, of a relevant medicinal product which may be placed on the market in that State without a marketing authorization by virtue of legislation adopted by that State under Article 5(1) of the Directive; and

(c) the sale, offer for sale or supply of an unauthorised medicinal product where the Secretary of State has temporarily authorised the distribution of that product under Article 5(2) of the Directive.".

Marginal Citations

M5 S.I.2005/2789.

Signed by authority of the Secretary of State for Health.

Department of Health
6th May 2009

Dawn Primarolo
Minister of State,

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations make further amendments to the Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, the Medicines for Human Use (Clinical Trials) Regulations 2004 and the Medicines for Human Use (Manufacturing, Wholesale Dealing and Miscellaneous Amendments) Regulations 2005 in connection with the transposition of Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use ("the 2001 Directive") and Directive 2001/20/EC of the European Parliament and of the Council on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use.

Regulation 2 amends the Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994 to disapply the labelling requirements in Schedule 5 to those Regulations (which are supplementary to the requirements in Title V of the 2001 Directive) to antiviral medicines in solutions for children under one year of age whilst a disease which poses a serious risk, or potentially poses a serious risk, to human health is pandemic or imminently pandemic where the medicine is for the purpose of treating that disease. Instead of the disapplied requirements, the container of the medicine needs to be labelled to show only the name of the child to be treated, the date on which the medicine was dispensed and the necessary and usual instructions for proper use.

Regulation 3 amends the Medicines for Human Use (Clinical Trials) Regulations 2004 to allow for notice of urgent safety measures (taken in order to protect the subjects of a clinical trial against any immediate hazard to their health or safety and the circumstances giving rise to those measures) to be given as soon as possible to the licensing authority and an ethics committee established under Part 2 of those Regulations during a period in which a disease is pandemic and is a serious risk to human health or potentially a serious risk to human health.

Regulation 4 of these Regulations amends regulation 8 of the Medicines for Human Use (Manufacturing, Wholesale Dealing and Miscellaneous Amendments) Regulations 2005 to enable the wholesale distribution of unauthorised medicinal products in response to the suspected or confirmed spread of pathogenic agents, toxins, chemical agents or nuclear radiation which could cause harm. It also incidentally corrects an erroneous reference in paragraph (3)(b) of that regulation to Article 5(2) of the 2001 Directive.

An Impact Assessment has been prepared in respect of these Regulations which is available from the Medicines and Healthcare products Regulatory Agency, Market Towers, 1 Nine Elms Lane, London SW8 5NQ.

Status:
Point in time view as at 08/05/2009.

Changes to legislation:
There are currently no known outstanding effects for the The Medicines for Human Use (Miscellaneous Amendments) Regulations 2009.