STATUTORY INSTRUMENTS

2005 No. 1710

MEDICINES

The Medicines (Provision of False or Misleading Information and Miscellaneous Amendments) Regulations 2005

Made - - - -	*24th June 2005*
Laid before Parliament	*1st July 2005*
Coming into force-	*1st August 2005*

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 upon her by the said section 2(2), the Secretary of State, the Department of Health, Social Services and Public Safety and the Department of Agriculture and Rural Development acting jointly, in exercise of the powers conferred upon them by sections 47(1) and 129(5) of the Medicines Act 1968(**c**), or, as the case may be, the powers conferred by the said provisions and now vested in them(**d**), and of all other powers enabling them in that behalf, after consulting, pursuant to section 129(6) of that Act, such organisations as appear to them to be representative of interests likely to be substantially affected by these Regulations, hereby make the following Regulations:—

Citation and commencement

1. These Regulations may be cited as the Medicines (Provision of False or Misleading Information and Miscellaneous Amendments) Regulations 2005 and shall come into force on 1 August 2005.

Amendment of the Medicines (Standard Provisions for Licences and Certificates) Regulations 1971

2.—(1) The Medicines (Standard Provisions for Licences and Certificates) Regulations 1971(**e**) are amended in accordance with the following provisions of this regulation.

(2) In regulation 2 (interpretation), in paragraph (1)—

(a) after the definition of "BCG vaccine"(**f**) insert the following definitions—

(**a**) 1972 c.68.
(**b**) S.I. 1972/1811.
(**c**) 1968 c.67.
(**d**) In the case of the Secretary of State, by virtue of articles 2(1) and 5 of, and the Schedule to, S.I. 1999/3142, and articles 3(7) of and 5(2) of, and the Schedule to, S.I. 2002/794; and in the case of the Department of Health, Social Services and Public Safety and the Department of Agriculture and Rural Development, the powers vested in the Ministers in charge of those Departments by virtue of section 95(5) of, and paragraph 10 of Schedule 12 to, the Northern Ireland Act 1998 (c.47) may now be exercised by the Departments by virtue of section 1(8) of, and paragraph 4(1)(b) of the Schedule to, the Northern Ireland Act 2000 (c.1). The Departments were re-named by virtue of Article 3(4) and (6) of S.I. 1999/283 (N.I.1).
(**e**) S.I. 1971/972; relevant amendments were made by S.I. 1977/1053, 1983/1730, 1992/2846, 1993/833, 1994/103, 2002/236 and 2003/2321.
(**f**) The definition of "BCG vaccine" was inserted by regulation 2 of S.I. 1977/675.

""biological medicinal product" means a product, the active substance of which is a biological substance;

"biological substance" means a substance that is produced by or extracted from a biological source and that needs for its characterisation and the determination of its quality a combination of physico-chemical-biological testing, together with the production process and its control;"; and

(b) after the definition of "imported proprietary product"(**a**) insert the following definition—

""intermediate product" means a substance, other than a starting material, which—

(a) has been manufactured for use in the manufacture of medicinal products, and

(b) is intended for further processing by a manufacturer of such products;".

(3) In Schedule 1 (standard provisions for product licences), in Part I, in paragraph 16(**b**) omit the words "as amended".

(4) In Schedule 2 (standard provisions for manufacturer's licences)—

(a) after paragraph 8A(**c**) insert the following paragraph—

"**8AA.** The licence holder shall keep readily available for examination by a person authorised by the licensing authority durable records of the details of manufacture of any intermediate products held by him which are for use in the manufacture of biological medicinal products for human use, and these records shall—

(a) be in such form as to ensure that the licence holder has a comprehensive record of all matters that are relevant to an evaluation of the safety, quality and efficacy of any finished biological medicinal product for human use which he manufactures using those intermediate products; and

(b) not be destroyed without the consent of the licensing authority until the records of the details of manufacture of any finished medicinal products which were or may be manufactured using those intermediate products may, in accordance with paragraph 8 above, be destroyed.";

(b) in paragraph 8B(**d**), for "8 or 8A" substitute "8, 8A or 8AA"; and

(c) after paragraph 17(**e**) insert the following paragraph—

"**18.** The licence holder shall take all reasonable precautions and exercise all due diligence to ensure that any information he provides to the licensing authority which is relevant to an evaluation of the safety, quality or efficacy of—

(a) any medicinal product for human use which he manufactures; or

(b) any starting materials or intermediate products that he holds which are for use in the manufacture of medicinal products for human use,

is not false or misleading in a material particular.".

(5) In Schedule 3 (standard provisions for wholesale dealer's licences)—

(a) in paragraph 7A(3)(a)(**f**), for "Articles 23 and 24 of the Second Council Directive" substitute "Articles 49 and 50 of the 2001 Directive(**g**)"; and

(b) after paragraph 9(**h**) insert the following paragraph—

"**10.** The licence holder shall take all reasonable precautions and exercise all due diligence to ensure that any information he provides to the licensing authority which is

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(**a**) The definition of "imported proprietary product" was inserted by regulation 2 of S.I. 1977/1053.
(**b**) Inserted by S.I. 1993/2539 and amended by S.I. 2002/236 and 2003/2321.
(**c**) Inserted by S.I. 1992/2846.
(**d**) Inserted by S.I. 1992/2846.
(**e**) Inserted by S.I. 1983/1730.
(**f**) Paragraph 7A was inserted by S.I. 1993/833 and amended by S.I. 2002/236.
(**g**) OJ L311, 28.11.2001, p.67.
(**h**) Inserted by S.I. 1983/1730.

relevant to an evaluation of the safety, quality or efficacy of any medicinal product for human use which he handles, stores or distributes is not false or misleading in a material particular.".

Amendment of the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994

3. In Schedule 3 of the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994(**a**) (offences, penalties etc.)—

(a) after paragraph 10 insert the following paragraph—

"**10A.**—(1) Any person who in the course of an application for the grant, renewal or variation of a marketing authorization for a relevant medicinal product—

(a) fails to provide to the licensing authority any information which is relevant to an evaluation of the safety, quality or efficacy of the relevant medicinal product as required by point (7) or (11) of the introduction to Annex I to the 2001 Directive(**b**); or

(b) provides to the licensing authority any information which is relevant to an evaluation of the safety, quality or efficacy of the relevant medicinal product but which is false or misleading in a material particular,

shall be guilty of an offence.

(2) Any person who—

(a) is responsible for placing a relevant medicinal product on the market;

(b) is the marketing authorization holder for a relevant medicinal product; or

(c) while employed or engaged as an appropriately qualified person responsible for pharmacovigilance for the purposes of Chapter 3 of Title II of Council Regulation (EEC) No 2309/93(**c**) or Title IX of the 2001 Directive is required to provide information to the licensing authority about a relevant medicinal product,

who provides to the licensing authority any information which is relevant to an evaluation of the safety, quality or efficacy of the relevant medicinal product but which is false or misleading in a material particular shall be guilty of an offence.";

(b) after paragraph 13 insert the following paragraph—

"**13A.** Any person who—

(a) sells or supplies a relevant medicinal product in accordance with any of paragraphs 1 to 4 of Schedule 1; or

(b) provides a specification for such a product for the purposes of paragraph 1 of that Schedule,

who provides to the licensing authority any information which is relevant to an evaluation of the safety, quality or efficacy of the relevant medicinal product but which is false or misleading in a material particular shall be guilty of an offence.";

(c) in paragraph 15, for "8, 9 or 10" substitute "8, 9, 10 or 10A"; and

(d) after paragraph 16 insert the following paragraph—

"**17.**—(1) A person does not commit an offence under paragraph 10A or 13A if he took all reasonable precautions and exercised all due diligence to avoid the commission of that offence.

(**a**) S.I. 1994/3144; Schedule 3 has been amended by S.I. 1998/3105, 2000/292, 2002/236 and 2003/2321.
(**b**) See the definition of "the 2001 Directive" in regulation 1(2); Annex I was substituted by Commission Directive 2003/63/EC (OJ L159, 27.6.2003, p.46).
(**c**) OJ No. L214, 24.8.93, p.1.

(2) Where evidence is adduced which is sufficient to raise an issue with respect to that defence, the court or jury shall assume that the defence is satisfied unless the prosecution proves beyond reasonable doubt that it is not.".

Signed by authority of the Secretary of State for Health

Jane Kennedy
Minister of State,
22 June 2005 Department of Health

Sealed with the Official Seal of the Department of Health, Social Services and Public Safety

D G Gowdy
Permanent Secretary,
23 June 2005 Department of Health, Social Services and Public Safety

Sealed with the Official Seal of the Department of Agriculture and Rural Development

Pat Toal
Permanent Secretary,
24 June 2005 Department of Agriculture and Rural Development

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations make amendments to: the Medicines (Standard Provisions for Licences and Certificates) Regulations 1971 ("the Standard Provisions Regulations"), which amongst other matters set the standard conditions for licences to manufacture or distribute by way of wholesale dealing medicinal products in the United Kingdom and which implement in part Titles IV and VII of Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use(**a**); and the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994 ("the Marketing Authorisations Regulations"), which relate to the scheme for authorising the marketing of medicinal products for human use in the United Kingdom and which implement various provisions of Directive 2001/83/EC, as amended.

Regulation 2 amends the Standard Provisions Regulations. A new requirement is imposed on holders of manufacturer's licences to keep detailed records in relation to intermediate products used in the manufacture of biological medicinal products for human use. Holders of manufacturer's and wholesale dealer's licences are also required to take all reasonable precautions and exercise all due diligence to ensure that any information they provide to the licensing authority which is relevant to the evaluation of the safety, quality and efficacy of medicinal products for human use that they manufacture or deal in is not false or misleading in a material particular. Manufacturers are also required to take all reasonable precautions and exercise all due diligence to ensure that the information they provide about starting materials and intermediate products used in the manufacture of medicinal products for human use is not false or misleading in a material particular. Paragraphs (2) and (4)(a) correct minor errors arising from the Medicines (Codification Amendment Etc.) Regulations 2002, which updated the references in United Kingdom legislation to certain European Community instruments relating to medicinal products for human use to take account of the adoption of Directive 2001/83/EC.

Regulation 3 amends the Marketing Authorisations Regulations. It creates new criminal offences for failures to provide information relevant to the evaluation of safety, quality or efficacy of a medicinal product for human use and for the provision of information to the licensing authority which is relevant to an evaluation of the safety, quality or efficacy of medicinal products for human use but which is false or misleading in a material particular. These offences relate to obligations under Directive 2001/83/EC; in particular the obligation on applicants for authorisation to provide all information relevant to an evaluation of a product's safety, quality and efficacy (see Article 8 and the introduction to Annex I of Directive 2001/83/EC) and to keep this information up to date (Articles 23, 24 and 106(6)) and the obligation on competent authorities to evaluate products' safety, quality and efficacy both on receipt of an application for authorisation and during the currency of a marketing authorisation (see Articles 19, 21, 24, 26, 107 and 116).

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.

(**a**) OJ No. L 311 28.11.2001, p.67.

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