Jersey Law 35/2002

MEDICINES (AMENDMENT) (JERSEY) LAW 2002

A LAW to amend the Medicines (Jersey) Law 1995; sanctioned by Order of Her Majesty in Council of the

22nd day of OCTOBER 2002

(Registered on the 8th day of November 2002)

STATES OF JERSEY

The 28th day of May 2002

THE STATES, subject to the sanction of Her Most Excellent Majesty in Council, have adopted the following Law -

ARTICLE 1

In this Law the "principal Law" means the Medicines (Jersey) Law 1995,[1] as amended.[2]

ARTICLE 2

Article 1 of the principal Law[3] shall be amended -

(a) by inserting in paragraph (1), after the definition "manufacture", the following definition -

[1] Volume 1994-1995, page 431.
[2] Volume 1999, page 420.
[3] Volume 1994-1995, page 439.

" 'marketing authorization' means a marketing authorisation as defined by the Marketing Authorisations for Veterinary Medical Products Regulations 1994 or a marketing authorization as defined by the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994, both Regulations being Regulations made under section 2(2) of the European Communities Act 1972 of the United Kingdom;";

(b) by substituting for the definition "United Kingdom product licence" in paragraph (1) the following definition -

" 'United Kingdom product licence' means a licence granted for the purposes of section 7 of the Medicines Act;".

ARTICLE 3

Article 7 of the principal Law[4] shall be repealed and the following Article substituted -

"ARTICLE 7

Licences and certificates

(1) Subject to paragraph (2), the Committee shall be responsible for the grant, renewal, variation, suspension and revocation of licences and certificates for the purposes of this Law.

(2) A valid United Kingdom product licence or a valid marketing authorization shall, subject to paragraphs (4) and (5), have effect for the purposes of this Law as though it were a product licence granted by the Committee for the purposes of Article 8.

[4] Volume 1994-1995, page 449.

(3) Accordingly in Article 8 a reference to a product licence shall be taken to include a reference to a United Kingdom product licence or a marketing authorization.

(4) A United Kingdom product licence or a marketing authorization shall not have effect for the purposes of this Law for a period of one month following the date on which it comes into effect.

(5) The Committee may, after consultation with the Advisory Council, in relation to a United Kingdom product licence or a marketing authorization, prescribe that the licence or authorization shall not have effect for the purposes of this Law.".

ARTICLE 4

For Article 19(3) of the principal Law[5] there shall be substituted the following paragraph -

"(3) An application for a product licence shall not be made in respect of medicinal products in respect of which there is in existence a United Kingdom product licence or a marketing authorization unless the Committee has prescribed, under paragraph (5) of Article 7, that the product licence or authorization shall be of no effect for the purposes of this Law.".

ARTICLE 5

For paragraphs (6) and (7) of Article 25 of the principal Law[6] there shall be substituted the following paragraphs -

"(6) Subject to paragraph (7), a United Kingdom product licence or a marketing authorization which has effect for the purposes of this Law shall continue in effect for those purposes for so long as it remains in effect in the United Kingdom.

[5] Volume 1994-1995, page 462.
[6] Volume 1994-1995, page 470.

(7) Except as provided by paragraph (8), if a United Kingdom product licence or a marketing authorization which has effect for the purposes of this Law is modified on renewal it shall continue to have effect for those purposes.

(8) The Committee may, after consultation with the Advisory Council, determine that the licence or authorization as so modified shall no longer have effect for the purposes of this Law.".

ARTICLE 6

Article 44 of the principal Law[7] shall be repealed and the following Article substituted -

"ARTICLE 44

Offences under Part III

(1) Subject to Article 45, a person who contravenes a provisions of Article 8, 9, 32, 33, 35 or 41 or who is in possession of a medicinal product or animal feeding stuff for the purpose of selling, supplying or exporting it in contravention of any of those Articles, shall be guilty of an offence.

(2) If a medicinal product or animal feeding stuff is imported in contravention of Article 8, 32, 33 or 41, a person who otherwise than for the purpose of performing or exercising a duty or power imposed or conferred by or under this Law or any other enactment, is in possession of the product or feeding stuff knowing or having reasonable cause to suspect that it was so imported shall be guilty of an offence.

(3) A person who, being the holder of a product licence, or of a United Kingdom product licence or a marketing authorization which has effect for the purposes of this Law, or of a clinical trial certificate, procures another person to carry out a

[7] Volume 1994-1995, page 493.

process in the manufacture or assembly of medicinal products of a description to which the licence, authorization or certificate relates, and -

(a) does not communicate to that person the provisions of the licence, authorization or certificate which are applicable to medicinal products of that description; or

(b) in a case where any of those provisions has been varied by a decision of the Committee, or in the case of a United Kingdom product licence or marketing authorization by the licensing authority, does not communicate the variation to that person within 14 days after the notice of the decision has been served on him;

shall be guilty of an offence.

(4) A person who, being the holder of a product licence, or a United Kingdom product licence or a marketing authorization which has effect for the purposes of this Law, sells or supplies a substance or article to which the licence or authorization relates to another person for the purpose of its being incorporated in animal feeding stuff, and does not communicate to that person any provisions of the licence, authorization or certificate which relate to the incorporation of that substance or article in animal feeding stuffs, or any instructions required by the licence or authorization to be communicated by him to persons to whom the substance or article is sold or supplied for that purpose, shall be guilty of an offence.

(5) Where any such provisions of a product licence, or a United Kingdom product licence or marketing authorization which has effect for the purposes of this Law as are mentioned in paragraph (4) are varied by the Committee or, as the case may be, the licensing authority, and on varying those provisions the Committee or the licensing authority serves on the holder of the

licence or authorization a notice requiring him, within such time (not being less than 14 days from the date of service of the notice) as may be specified in the notice, to take such steps as may be specified for making the variation known, either generally or to persons or classes of persons specified in the notice, then if the holder of the licence or authorization does not comply with the requirements of that notice he shall be guilty of an offence.

(6) A person who, in giving information which he is required to give under Article 43, makes a statement which he knows to be false in a material particular shall be guilty of an offence.

(7) A person who without reasonable excuse fails to comply with a requirement imposed on him by a notice under paragraph (2) of Article 43 shall be guilty of an offence.

(8) A person guilty of an offence under any of paragraphs (1) to (6) shall be liable to imprisonment for a term not exceeding two years or to a fine or to both.

(9) A person guilty of an offence under paragraph (7) shall be liable to a fine not exceeding level 2 on the standard scale.[8]

(10) In this Article 'the licensing authority' -

(a) in relation to a United Kingdom product licence, has the same meaning as in section 6 of the Medicines Act;

(b) in relation to a marketing authorization that is a marketing authorisation as defined by the Veterinary Medicines Products Regulations 1994 of the United Kingdom, means the Ministers as defined in those

[8] Volume 1992-1993, page 437.

Regulations or any one of those Ministers acting alone or any two or more of them acting jointly;

(c) in relation to a marketing authorization which is a Community marketing authorization as defined by the medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994 of the United Kingdom, means the European Commission; and

(d) in relation to a marketing authorization which is a United Kingdom marketing authorization as defined by the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994 of the United Kingdom, means the licensing authority under those Regulations.".

ARTICLE 7

Article 89 of the principal Law[9] shall be repealed and the following Article substituted -

"ARTICLE 89

Advertisements requiring consent of holder of product licence or marketing authorization

(1) Where a product licence under this Law is in force, or a United Kingdom product licence or a marketing authorization has effect for the purposes of this Law, which (in each case) is applicable to medicinal products of a particular description, then, except with the consent of the holder of the licence or authorization -

(a) no commercially interested party (other than the holder of the licence or authorization) shall issue, or cause another person to issue, any advertisement relating to medicinal products of that description; and

[9] Volume 1994-1995, page 546.

(b) no person who is not a commercially interested party shall, at the request or with the consent of a commercially interested party issue, or cause another person to issue, any such advertisement.

(2) Subject to Article 104, a person who contravenes the provisions of this Article shall be guilty of an offence and liable to a fine not exceeding level 2 on the standard scale.[10]".

ARTICLE 8

A provision of the principal Law specified in column 1 of the Schedule to this Law shall be amended by deleting from it the words specified in column 2 of that Schedule and substituting the words specified in column 3.

ARTICLE 9

This Law may be cited as Medicines (Amendment) (Jersey) Law 2002 and shall come into force on the seventh day following its registration.

M.N. DE LA HAYE

Deputy Greffier of the States.

[10] Volume 1992-1993, page 437.

SCHEDULE

(Article 8)

ADDITIONAL AMENDMENTS TO PRINCIPAL LAW

Column 1	*Column 2*	*Column 3*
Provision of principal Law	*Words to be deleted*	*Words to be substituted*
24(1)(a)[11]	"United Kingdom product licence"	"United Kingdom product licence or marketing authorization"
24(1)(b)[11]	"such a product licence"	"such a product licence or authorization"
24(1)[11]	"that product licence"	"that product licence or authorization"
41(2)(a)[12]	"United Kingdom product licence"	"United Kingdom product licence or marketing authorization"
41(3)(a)[12]	"United Kingdom product licence"	"United Kingdom product licence or marketing authorization"

[11] Volume 1994-1995, page 467.
[12] Volume 1994-1995, page 489.

Column 1	*Column 2*	*Column 3*
Provision of principal Law	*Words to be deleted*	*Words to be substituted*
41(3)(b)[13]	"such a licence"	"such a licence or authorization"
42(4)[14]	"United Kingdom product licence"	"United Kingdom product licence or a marketing authorization"
45(1)[15]	"United Kingdom product licence"	"United Kingdom product licence or marketing authorization"
45(1)[16]	"that licence or certificate"	"that licence, authorization or certificate"
58(1)(b)[17]	"United Kingdom product licence"	"United Kingdom product licence or marketing authorization"
58(1)(c)[17]	"that licence"	"that licence or authorization"

[13] Volume 1994-1995, page 489.
[14] Volume 1994-1995, page 491.
[15] Volume 1994-1995, page 495.
[16] Volume 1994-1995, page 496.
[17] Volume 1994-1995, page 509.

Column 1	*Column 2*	*Column 3*
Provision of principal Law	*Words to be deleted*	*Words to be substituted*
60(a)[18]	"United Kingdom product licence"	"United Kingdom product licence or a marketing authorization"

[18] Volume 1994-1995, page 512.