SCHEDULES

SCHEDULE 32

Regulation 347

Transitional provisions and savings

Continuity of the law

1.—(1) This paragraph applies where any provision of these Regulations re-enacts (with or without modification) an enactment or instrument repealed or revoked by these Regulations.

(2) The repeal and re-enactment do not affect the continuity of the law.

(3) Anything done, or having effect as if done, under or for the purposes of the repealed provision that could have been done under or for the purposes of the corresponding provision of these Regulations, if in force or effective immediately before the commencement of that corresponding provision, has effect thereafter as if done under or for the purposes of that corresponding provision.

(4) Any reference (express or implied) in these Regulations or any other enactment, instrument or document to a provision of these Regulations is to be construed (so far as the context permits) as including, as respects times, circumstances or purposes in relation to which the corresponding repealed provision had effect, a reference to that corresponding provision.

(5) Any reference (express or implied) in any enactment, instrument or document to a repealed provision is to be construed (so far as the context permits), as respects times, circumstances and purposes in relation to which the corresponding provision of these Regulations has effect, as being or (according to the context) including a reference to the corresponding provision of these Regulations.

(6) This paragraph has effect subject to any specific transitional provision or saving in this Schedule.

Product licences

2.—(1) This paragraph applies to a marketing authorisation that—

(a) became a marketing authorisation on 1st January 1995 by virtue of paragraph 1 of Schedule 6 [M1] to the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994 (conversion of existing product licences); and

(b) by virtue of paragraph 1 of this Schedule, has effect from the coming into force of these Regulations as a marketing authorisation granted under these Regulations.

(2) The following provisions do not apply in relation to the marketing authorisation—

(a) regulation 68(7) (revocation etc of marketing authorisation because the holder has ceased to be established in the EU); and

(b) regulation 258 (packaging requirements: specific provisions).

(3) Paragraph (4) applies if the marketing authorisation has not been renewed in the period beginning with 1st January 1995 and ending when these Regulations come into force.

(4) The Medicines (Labelling) Regulations 1976 [M2] and the Medicines (Leaflets) Regulations 1977 [M3] (and subsequent regulations amending those regulations) in so far as they relate to medicinal products continue to have effect in relation to the product to which the marketing authorisation relates until the marketing authorisation is renewed.

Marginal Citations

M1 S.I. 1994/3144, as amended by S.I. 2004/3224 and S.I. 2005/2759. There are other amendments to those regulations that are not relevant to this paragraph..

M2 S.I. 1976/1726, as amended by S.I. 1977/996 and 2168, S.I. 1978/41 and 1140, S.I. 1981/1791, S.I. 1983/1729, S.I. 1985/1558 and 2008, S.I. 1988/1009, S.I. 1989/1183, S.I. 1992/3273, S.I. 1994/104 and 3144, S.I. 2002/236, S.I. 2004/1031 and S.I. 2005/2745 and 2753.

M3 S.I. 1977/1055, as amended by S.I. 1992/3274, 1994/104 and 3144, and 2005/2753..

Product licences of right

3.—(1) This paragraph applies to a product licence of right.

(2) In this paragraph, "product licence of right" means a licence of right within the meaning of section 25(4) of the Medicines Act 1968 that—

(a) has been issued in relation to the requirements to hold a product licence contained in section 7(2) of that Act; and

(b) is in force immediately before the coming into force of these Regulations.

(3) A product licence of right shall continue in force, subject to the following sub-paragraphs.

(4) Parts 4 to 11, 13 and 14 of these Regulations shall not apply in relation to a medicinal product that is the subject of a product licence of right, except as provided in the following sub-paragraphs.

(5) A medicinal product to which a product licence of right relates shall—

(a) continue to be classified as a prescription only medicine, a medicinal product not subject to general sale, or a medicinal product subject to general sale, as the case may be, in accordance with the provisions of the Medicines Act 1968 and any statutory instrument made under that Act that was in force immediately before the coming into force of these regulations; and

(b) shall be treated as a prescription only medicine, a pharmacy medicine not subject to general sale, or a medicine subject to general sale respectively, as the case may be, for the purposes of Part 12 of these Regulations.

(6) The provisions listed in sub-paragraph (7), and any provisions to which they refer, shall continue to have effect as they did immediately before the coming into force of these Regulations in relation to a product licence of right and to the product to which it relates.

(7) Those provisions are—

(a) section 28(1), (2) and (3)(a) to (e) and (g) to (j) (general power to suspend, revoke or vary licences) of the Medicines Act 1968 [M4];

(b) the Medicines (Advertising of Medicinal Products) (No. 2) Regulations 1975 [M5];

(c) the Medicines (Labelling) Regulations 1976 [M6];

(d) the Medicines (Leaflets) Regulations 1977 [M7]; and

(e) the Medicines (Labelling and Advertising to the Public) Regulations 1978 [M8].

(8) Part 1 of Schedule 11 (advice and representations) shall have effect where the licensing authority proposes to exercise any power conferred by section 28 of the Medicines Act referred to in sub-paragraph 7(a) in relation to a product licence of right, as if that proposal concerned the suspension, revocation or variation of a UK marketing authorisation, certificate of registration or traditional herbal registration under these Regulations.

(9) Without prejudice to any requirement of Part 1 of Schedule 11 as to the service of notices, where in the exercise of any such power the licensing authority suspends, revokes or varies a product

licence of right, it must serve a notice on the holder a notice giving particulars of the suspension, revocation or variation and of the reasons for its decision to suspend, vary or revoke the product licence of right.

(10) Regulations **[**F1268 (offences relating to packaging and package leaflets in Great Britain: authorisation holders), 268A (offences relating to packaging and package leaflets in Northern Ireland: authorisation holders), 269 (offences relating to packaging and package leaflets in Great Britain: other persons), 269A (offences relating to packaging and package leaflets in Northern Ireland: other persons)**]** and 271 (offences: penalties) shall have effect in relation to the provisions in sub-paragraph (7)(d) as if—

(a) references to the holder of a marketing authorisation included reference to the holder of a product licence of right; and

(b) the provisions in sub-paragraph (7)(d) were requirements of Part 13.

(11) A product licence of right shall cease to be in force at the same time that a marketing authorisation, certificate of registration or traditional herbal registration is granted in respect of the product to which the product licence of right relates.

Textual Amendments

F1 Words in Sch. 32 para. 3(10) substituted (31.12.2020) by S.I. 2019/775, **reg. 224ZD** (as inserted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 183**)

Marginal Citations

M4 Section 28(3) was amended by Schedule 1 to the Animal Health and Welfare Act 1984 (1984 c.40), regulation 4(5) of S.I. 1977/1050, regulation 2(2) of S.I. 1975/1169, regulation 6(2) of S.I. 1994/276, regulation 2(a)(iii) of S.I. 2002/236 and paragraph 14 of Schedule 8 to S.I. 2006/2407.

M5 S.I. 1975/1326, as amended by S.I. 1979/1760 and S.I. 1994/1932.

M6 S.I. 1976/1726, as amended by S.I. 1977/996, S.I. 1977/2168, S.I. 1978/41, S.I. 1978/1140, S.I. 1981/1791, S.I. 1983/1729, S.I. 1985/1558, S.I. 1985/2008, S.I. 1988/1009, S.I. 1989/1183, S.I. 1992/3273, S.I. 1994/104S.I. 1994/3144, S.I. 2002/236, S.I. 2004/1031, S.I. 2005/2745 and S.I. 2005/2753.

M7 S.I. 1977/1055, as amended by S.I. 1992/3274, S.I. 1994/104, S.I. 1994/3144, and S.I. 2005/2753.

M8 S.I. 1978/41, as amended by S.I. 2004/1771.

Classification of UK marketing authorisation and certificate of registration

4.—(1) Sub-paragraph (3) applies to a UK marketing authorisation granted before 1st April 2002 if—

(a) the authorisation contains a statement that the product to which the authorisation relates is to be available on one or more of the bases set out in paragraph (2); or

(b) the product to which the authorisation relates is to be available on one or more of the bases set out in paragraph (2) by virtue of any enactment in force immediately before the coming into force of these Regulations.

(2) Those bases are that the product is to be available—

(a) only on prescription;

(b) only from a pharmacy; or

(c) on general sale.

(3) It is a condition of the UK marketing authorisation that the product is only to be available on that basis or those bases.

Advanced therapy medicinal products

5. No provision of these Regulations that applies only to advanced therapy medicinal products shall apply until 30th December 2012 to advanced therapy medicinal products which—

(a) are tissue engineered products; and

(b) were legally on the market in the United Kingdom in accordance with United Kingdom or European Union legislation on 30th December 2008.

*Medicines for Human Use (Advanced Therapy Medicinal Products and Miscellaneous Amendments) Regulations 2010 (*S.I. 2010/1882*)*

6. Regulation 9 (amendment of the Medicines for Human Use (Clinical Trials) Regulations 2004) of the Medicines for Human Use (Advanced Therapy Medicinal Products and Miscellaneous Amendments) Regulations 2010 [M9] remains in force.

Marginal Citations

M9 S.I. 2010/1882.

Section 60 of the Medicines Act 1968 etc

7.—(1) Section 60 of the Medicines Act 1968 ("the Act") shall continue to have effect insofar as it relates to the making of, and continued operation of, the Medicines (Administration of Radioactive Substances) Regulations 1978 [M10] ("the 1978 Regulations").

(2) The following provisions of the Act shall continue to have effect as they did immediately before the coming into force of these Regulations in relation to the following provisions of the 1978 Regulations—

(a) section 22A(2) to (9) and 10(b) (hearing before person appointed) of the Act, in relation to regulation 7 (hearings and written representations) of the 1978 Regulations;

(b) section 67(2) and (4) (offences under Part III) of the Act, as they relate to section 60 of the Act, in relation to regulation 8 (application of provisions of the Act) of the 1978 Regulations; and

(c) paragraphs 7, 8, 9(3) and 10 to 12 of Schedule 1A (provisions relating to Commission and committees) to the Act [M11], in relation to the committee established under regulation 3 (advisory committee) of the 1978 Regulations.

Marginal Citations

M10 S.I. 1978/1006, as amended by S.I. 1995/2147, S.I. 2005/2754. S.I. 2006/2407 and S.I. 2006/2806.

M11 1968 c.67. Schedule 1A was inserted by regulation 7(2) of S.I. 2005/1094.

Changes to legislation:
There are currently no known outstanding effects for the The Human Medicines Regulations 2012, SCHEDULE 32.