STATUTORY INSTRUMENTS

2019 No. 818

The Taxes (Amendments) (EU Exit) (No. 2) Regulations 2019

PART 2

Amendments to primary legislation

Corporation Tax Act 2010

8.—(1) The Corporation Tax Act 2010(**1**) is amended as follows.

(2) In section 357B(4)(a) for "section 357BB" substitute "sections 357BB and 357BBA".

(3) In section 357BB—

(a) in subsection (1)—

(i) at the end of paragraph (d) insert "and";

(ii) omit paragraph (f);

(b) for subsections (3) to (5) substitute—

"(3) Where a product benefits from marketing protection (see subsection (4)) or data protection (see subsection (5)), the person who holds the relevant marketing authorisation in respect of the product (see subsection (6A)) is to be treated for the purposes of this Part as having been granted a right to which this Part applies in respect of the product.

(4) A product benefits from marketing protection if—

(a) a marketing authorisation under the Human Medicines Regulations 2012(**2**) has been granted in respect of the product and the period during which a generic of the product may be prevented from being sold by reason of regulation 51(8) of those Regulations has not expired;

(b) an orphan marketing authorisation under the Human Medicines Regulations 2012 has been granted in respect of the product and the prohibition arising in connection with that authorisation under regulation 58D(1) of those Regulations remains in force;

(c) a marketing authorisation to which paragraph 6 of Schedule 33A to the Human Medicines Regulations 2012 applies has been granted in respect of the product and the holder of the authorisation continues to benefit from marketing exclusivity by reason of sub-paragraph (4)(f) or (7) of that paragraph;

(d) a marketing authorisation under the Veterinary Medicines Regulations 2013(**3**) has been granted in respect of the product and the period during which an equivalent of the product may be prevented from being placed on the market by paragraph 11(3) of Schedule 1 to those Regulations has not expired.

(5) A product benefits from data protection if—

(**1**) 2010 c. 4. Sections 357B and 357BB were inserted by paragraph 1(1) of Schedule 2 to the Finance Act 2012 (c. 14).
(**2**) S.I. 2012/1916, relevantly amended by S.I. 2013/1855, S.I. 2013/2593, S.I. 2014/1878, S.I. 2019/62, S.I. 2019/775.
(**3**) S.I. 2013/2033, amended by S.I. 2014/599, S.I. 2018/761, S.I. 2019/676, S.I. 2019/788.

(a) a marketing authorisation in respect of the product under the Human Medicines Regulations 2012 has been granted or varied in circumstances giving rise to the prohibition in regulation 51(16) or 64A(3) of those Regulations and that prohibition remains in force;

(b) a marketing authorisation under Regulation (EC) No 1107/2009(**4**) has been granted in respect of the product and data relating to the product benefits from data protection under Article 59 of that Regulation.";

(c) in subsection (6) for "subsection (5)(c)" substitute "subsection (5)(b)";

(d) after subsection (6) insert—

"(6A) In subsection (3) the relevant marketing authorisation is the marketing authorisation by reference to which it is determined that the product benefits from marketing protection or data protection.";

(e) in subsection (7), in the appropriate place, insert—

""Regulation (EC) No 1107/2009" means Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market,";

(f) in subsection (8)—

(i) in paragraph (a) for "this section", in the second place where the expression occurs, substitute "subsection (3)";

(ii) omit paragraph (b).

(4) After section 357BB insert—

"**Rights to which this Part applies: EU rights**

357BBA.—(1) This Part applies to the following rights—

(a) an EU supplementary protection certificate, and

(b) any Community plant variety rights granted under Council Regulation (EC) No 2100/94(**5**).

(2) Where—

(a) a person holds a marketing authorisation in respect of any product in accordance with any legislation having effect in EU law, and

(b) the product benefits from EU marketing protection (see subsection (3)) or EU data protection (see subsection (4)),

the person is to be treated for the purposes of this Part as having been granted a right to which this Part applies in respect of the product.

(3) A product benefits from EU marketing protection if—

(a) the product benefits from marketing protection by virtue of Article 14.11 of Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medical products for human use(**6**), or

(b) any of the following prohibitions is in force—

(**4**) Regulation (EC) No 1107/2009 is amended by S.I. 2019/556.
(**5**) OJNo. L 227, 01.09.1994, p. 1.
(**6**) OJ No. L 136, 30.04.2004, p. 1, to which there are amendments not relevant to these Regulations.

(i) the prohibition on placing on the market a generic of the product imposed by Article 10.1 of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use(**7**),

(ii) the prohibition imposed by Article 8.1 of Regulation (EC) No 141/2000 of the European Parliament and the Council of 16 December 1999 on orphan medicinal products(**8**), and

(iii) the prohibition on placing on the market a generic of the product imposed by Article 13.1 of Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products(**9**).

(4) A product benefits from EU data protection if—

(a) the product benefits from the data exclusivity conferred by Article 10.5 of Directive 2001/83/EC of the European Parliament and of the Council,

(b) the prohibition on referring to the results of tests or trials in relation to the product imposed by Article 74a of that Directive is in force, or

(c) data relating to the product benefits from data protection under Article 59 of Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market(**10**).

(5) The reference to data in subsection (4)(c) does not include a study necessary for the renewal or review of a marketing authorisation granted in respect of the product in accordance with Regulation (EC) No 1107/2009.

(6) In this section "EU supplementary protection certificate" means a certificate issued under—

(a) Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products(**11**), or

(b) Regulation (EC) No 1610/96 of the European Parliament and of the Council of 23 July 1996 concerning the creation of a supplementary protection certificate for plant protection products(**12**).

(7) A reference in this section to any EU legislation is a reference to that legislation as it has effect in EU law.

(8) The Treasury may by regulations—

(a) amend this section so as to make provision about the circumstances in which a product benefits from EU marketing protection or EU data protection for the purposes of subsection (2);

(b) make such provision amending any reference in this section to EU legislation as appears to the Treasury appropriate in consequence of any EU legislation amending or replacing that EU legislation.

(9) Regulations under subsection (8) may make any incidental, supplemental, consequential, transitional or saving provision, including provision amending or modifying this Part.".

(**7**) OJ No. L 311, 28.11.2001, p. 67, relevantly amended by Directive 2004/27/EC OJ No. L 136, 30.04.2004, p.34.
(**8**) OJ No. L 18, 22.01.2000, p. 1, to which there are amendments not relevant to these Regulations
(**9**) OJ No. L 311, 28.11.2001, p. 1, relevantly amended by Directive 2004/28/EC OJ No. L 136, 30.04.2004, p.58.
(**10**) OJ No. L 309, 24.11.2009, p. 1, to which there are amendments not relevant to these Regulations.
(**11**) OJ No. L 152, 16.06.2009, p. 1.
(**12**) OJ No. L 198, 08.08.1996, p. 30.

(5) In section 1081(1) after "be" insert "UK resident or".

(6) In section 1127—

(a) in subsection (6) for the words from "the European Commission" to "international accounting standard" substitute "an international accounting standard has been adopted by the United Kingdom or the European Commission";

(b) in subsection (7) before the definition of "IAS accounts" insert—

""adopted by the United Kingdom" means adopted for use within the United Kingdom by virtue of Chapter 2 or 3 of Part 2 of the International Accounting Standards and European Public Limited-Liability Company (Amendment etc.) (EU Exit) Regulations 2019(**13**),

"adopted by the European Commission" means adopted by the European Commission in accordance with Regulation (EC) No 1606/2002 of the European Parliament and the Council of 19 July 2002 on the application of international accounting standards (as it has effect in EU law),(**14**)

(7) For section 1158(4)(c)(**15**) substitute—

"(c) a Gibraltar regulated market within the meaning given by Article 26(11)(b)(i) of that Regulation.".

(**13**) S.I. 2019/685.
(**14**) OJ No. L 243, 11.09.2002, p. 1.
(**15**) Section 1158 was substituted by section 49 of the Finance Act 2011 (c. 11) and relevantly amended by S.I. 2017/701 and S.I. 2019/689.