SCHEDULE 8 Regulation 229

Consequential provision

PART 1

Amendment of primary legislation

Amendment of the National Health Service Act 2006

1.—(1) Section 88 of the National Health Service Act 2006 [M1] (GMS contracts: prescription of drugs, etc) is amended as follows.

(2) In subsection (3), for "Community marketing authorization or United Kingdom" substitute " UK ".

(3) For subsection (4) substitute—

"(4) "UK marketing authorisation" has the meaning given by regulation 8(1) of the Human Medicines Regulations 2012 (S.I. 2012/1916) [M2].".

Commencement Information

I1 Sch. 8 para. 1 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Marginal Citations

M1 2006 c.41.

M2 S.I. 2012/1916.

Amendment of the Access to Medical Treatments (Innovation) Act 2016

2. In section 3(2)(b) and (4)(a), (b) and (c) of the Access to Medical Treatments (Innovation) Act 2016 [M3] (provision supplementary to section 2: database of innovative treatments) insert " UK " before "marketing authorisation".

Commencement Information

I2 Sch. 8 para. 2 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Marginal Citations

M3 2016 c.9.

PART 2

Amendment of secondary legislation

Amendment of the Medicines (Bal Jivan Chamcho Prohibition) (No 2) Order 1977

3. In article 2 of the Medicines (Bal Jivan Chamcho Prohibition) (No 2) Order 1977 (prohibition of sale, supply and importation of Bal Jivan Chamcho) [M4]—

(a) for paragraph (4) substitute—

"(4) The prohibition imposed by paragraph (1) does not apply where the medicinal product—

(a) is imported from an approved country for import; and

(b) is being, or is to be, exported to a country other than the United Kingdom."; and

(b) for paragraph (5) substitute—

"(5) In paragraph (4), "approved country for import" has the meaning given in regulation 8(1) of the Human Medicines Regulations 2012.".

Commencement Information

I3 Sch. 8 para. 3 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Marginal Citations

M4 S.I. 1977/670. Article 2 was amended by S.I. 1990/2487, 1997/856, 2008/548 and 2012/1809.

Amendment of the Prescription Only Medicines (Human Use) Order 1997

4. **[**[F1]After article 5(1)**]** of the Prescription Only Medicines (Human Use) Order 1997 (exempt medicinal products) [M5], **[**[F2]insert—

"(1A) In paragraph (1) "marketing authorisation" means—

(a) in relation to medicinal products for sale or supply in Great Britain, a UKMA(GB) or UKMA(UK);

(b) in relation to medicinal products for sale or supply in Northern Ireland, a UKMA(NI) or UKMA(UK), an EU marketing authorisation or a parallel import licence."**]**

Textual Amendments

F1 Words in Sch. 8 para. 4 substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 194(a)(i)**

F2 Words in Sch. 8 para. 4 substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 194(a)(ii)**

Commencement Information

I4 Sch. 8 para. 4 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Marginal Citations

M5 S.I. 1997/1830. Article 5(1) was amended by S.I. 2012/1916.

Amendment of the Medicines (Aristolochia and Mu Tong etc) (Prohibition) Order 2001

5.—(1) The Medicines (Aristolochia and Mu Tong etc) (Prohibition) Order 2001 [M6] is amended as follows.

(2) In article 1 (citation, commencement and interpretation) [M7]—

(a) omit the definitions of "free circulation in member States" and "third country"; and

(b) insert at the appropriate place—

""approved country for import" has the meaning given in regulation 8(1) of the Human Medicines Regulations 2012;".

(3) In article 4 (exceptions to the prohibition imposed by articles 2 and 3) [M8]—

(a) for paragraph (3) substitute—

"(3) The prohibition imposed by articles 2 and 3 does not apply where the medicinal product—

(a) is imported from an approved country for import; and

(b) is being, or is to be, exported to a country other than the United Kingdom."; and

(b) in paragraph (4), for "marketing authorisation, certificate of registration, traditional herbal registration or Article 126a authorisation" substitute " UK marketing authorisation, certificate of registration or traditional herbal registration ".

Commencement Information

I5 Sch. 8 para. 5 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Marginal Citations

M6 S.I. 2001/1841.

M7 Article 1 was amended by S.I. 2008/548 and 2012/1809.

M8 Article 4 was amended by S.I. 2008/548 and 2012/1916.

Amendment of the Medicines for Human Use (Kava-kava) (Prohibition) Order 2002

6.—(1) The Medicines for Human Use (Kava-kava) Prohibition) Order 2002 [M9] is amended as follows.

(2) In article 1 (citation, commencement and interpretation) [M10]—

(a) omit the definitions of "free circulation in member States" and "third country"; and

(b) insert at the appropriate place—

""approved country for import" has the meaning given in regulation 8(1) of the Human Medicines Regulations 2012;".

(3) In article 3 (exceptions to the prohibition imposed by article 2) [M11]—

(a) for paragraph (c) substitute—

"(c) imported from an approved country for import, and is being, or is to be, exported to a country other than the United Kingdom; or"; and

(b) in paragraph (d), for "marketing authorisation, certificate of registration, traditional herbal registration or Article 126a authorisation" substitute " UK marketing authorisation, certificate of registration or traditional herbal registration ".

Commencement Information

I6 Sch. 8 para. 6 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Marginal Citations

M9 S.I. 2002/3170.

M10 Article 1 was amended by S.I. 2008/548 and 2012/1809.

M11 Article 3 was amended by S.I. 2008/548 and 2012/1916.

Amendment of the Unlicensed Medicinal Products for Human Use (Transmissible Spongiform Encephalopathies) (Safety) Regulations 2003

[F3**7.** In regulation 1(2) of the Unlicensed Medicinal Products for Human Use (Transmissible Spongiform Encephalopathies) (Safety) Regulations 2003 (citation, commencement and interpretation), for the definition of "unlicensed product" substitute—

""unlicensed product" means—

(a) in the case of a product to be imported or marketed in Great Britain, a medicinal product for human use, other than an excluded medicine, in respect of which no UKMA(GB), UKMA(UK), THR(UK) or THR(GB) has been granted;

(b) in the case of a product to be imported or marketed in Northern Ireland, a medicinal product for human use, other than an excluded medicine, in respect of which no UKMA(NI), UKMA(UK), THR(UK) or THR(NI), EU marketing authorisation or Article 126a authorisation has been granted,

and "Article 126a authorisation", "EU marketing authorisation", "THR(GB)", "THR(NI)", "THR(UK)", "UKMA(GB)", "UKMA(NI)" and "UKMA(UK)" have the meanings given in regulation 8 of the 2012 Regulations;.;".**]**

Textual Amendments

F3 Sch. 8 para. 7 substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 194(c)**

Commencement Information

I7 Sch. 8 para. 7 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of the Blood Safety and Quality Regulations 2005

8. In regulation 1A of the Blood Safety and Quality Regulations 2005 M12, after paragraph (10) insert—

"(10A) Paragraph 7.1 is to be read **[**F4as if the reference**]** to "Directive 2003/94/EC" were to "the Good Manufacturing Practice Directive, within the meaning of **[**F5paragraph (a) of the definition of that term in**]** regulation 8(1) of the Human Medicines Regulations 2012.".

Textual Amendments

F4 Words in Sch. 8 para. 8 substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 194(b)(i)**

F5 Words in Sch. 8 para. 8 inserted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 194(b)(ii)**

Commencement Information

I8 Sch. 8 para. 8 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Marginal Citations

M12 S.I. 2005/50. Regulation 1A was inserted by S.I. 2019/4.

Amendment of the Natural Mineral Water, Spring Water and Bottled Drinking Water (England) Regulations 2007

9. In regulation 3(1)(a) of the Natural Mineral Water, Spring Water and Bottled Drinking Water (England) Regulations 2007 (exemptions) [M13] for "Directive" to the end substitute " regulation 2(1) of the Human Medicines Regulations 2012 ".

Commencement Information

I9 Sch. 8 para. 9 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Marginal Citations

M13 S.I. 2007/2785. Regulation 3(1)(a) was substituted by S.I. 2018/352.

Amendment of the Medicines for Human Use (Prohibition) (Senecio and Miscellaneous Amendments) Order 2008

10.—(1) The Medicines for Human Use (Prohibition) (Senecio and Miscellaneous Amendments) Order 2008 [M14] is amended as follows.

(2) In article 1 (citation, commencement and interpretation) [M15]—

(a) omit the definitions of "free circulation in member States" and "third country"; and

(b) insert at the appropriate place—

""approved country for import" has the meaning given in regulation 8(1) of the Human Medicines Regulations 2012;".

(3) In article 3 (exceptions to the prohibition imposed by article 2) [M16]—

(a) for paragraph (c) substitute—

"(c) is imported from an approved country for import, and is being, or is to be, exported to a country other than the United Kingdom; or"; and

(b) in paragraph (d), for "marketing authorisation, certificate of registration, traditional herbal registration or Article 126a authorisation" substitute " UK marketing authorisation, certificate of registration or traditional herbal registration ".

Commencement Information

I10 Sch. 8 para. 10 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Marginal Citations

M14 S.I. 2008/548.

M15 Article 1 was amended by S.I. 2012/1809.

M16 Article 3 was amended by S.I. 2012/1916.

Amendment of the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013

11.—(1) The National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 [M17] are amended as follows.

(2) In paragraph 8(10) of Schedule 4 (terms of service of NHS pharmacists: providing ordered drugs or appliances), insert " UK " before "marketing authorisation" in both places it appears.

(3) In paragraph 6(8) of Schedule 7 (mandatory terms for LPS schemes: providing ordered drugs or appliances), insert " UK " before "marketing authorisation" in both places it appears.

Commencement Information

I11 Sch. 8 para. 11 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Marginal Citations

M17 S.I. 2013/349.

Amendment of the Genetically Modified Organisms (Contained Use) Regulations 2014

12. In regulation 3(2)(b) of the Genetically Modified Organisms (Contained Use) Regulations 2014 (application) [M18], at the end insert—

"; or

(iv) a medicinal product for human use marketed in accordance with the Human Medicines Regulations 2012;".

Commencement Information

I12 Sch. 8 para. 12 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Marginal Citations

M18 S.I. 2014/1663.

Amendment of the Nicotine Inhaling Products (Age of Sale and Proxy Purchasing) Regulations 2015

13.—(1) The Nicotine Inhaling Products (Age of Sale and Proxy Purchasing) Regulations 2015 [M19] are amended as follows.

(2) In regulation 1(4) (citation, commencement and interpretation), insert " UK " before "marketing authorisation".

(3) In regulation 5(2)(c)(i) (exception for medicines indicated for the treatment of persons under 18), insert " UK " before "marketing authorisation".

Commencement Information

I13 Sch. 8 para. 13 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Marginal Citations

M19 S.I. 2015/895.

Amendment of the Genetically Modified Organisms (Contained Use) Regulations (Northern Ireland) 2015

14. In regulation 3(2)(b) of the Genetically Modified Organisms (Contained Use) Regulations (Northern Ireland) 2015 (application) [M20], at the end insert—

"; or

(iv) a medicinal product for human use marketed in accordance with the Human Medicines Regulations 2012;".

Commencement Information

I14 Sch. 8 para. 14 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Marginal Citations

M20 S.R. 2015 No. 339.

Amendment of the Health Service Products (Provision and Disclosure of Information) Regulations 2018

15. In regulation 29(4) of the Health Service Products (Provision and Disclosure of Information) Regulations 2018 [M21]—

(a) in the definition of "notifiable presentation"—

(i) insert " UK " before "marketing authorisation", and

(ii) omit from "other than" to the end;

(b) in the definition of "designated producer" insert " UK " before "marketing authorisation"; and

(c) in the definition of "marketing authorisation" insert " UK " before "marketing".

Commencement Information

I15 Sch. 8 para. 15 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Marginal Citations

M21 S.I. 2018/677.

Amendment of the Branded Health Service Medicines (Costs) Regulations 2018

16.—(1) The Branded Health Service Medicines (Costs) Regulations 2018 [M22] are amended as follows.

(2) In regulation 1(2) (interpretation)—

[F6](a) . . . . . .

[F6](b) . . . . . .

[F6](c) . . . . . .

[F6](d) . . . . . .

(e) in the definition of "supplementary protection certificate" omit from "means" to the end and insert " has the meaning given by section 128B(2) of the Patents Act 1977 ".

[F7](3) . . . . . .

(4) In regulation 9 (new presentation)—

(a) in paragraph (10)—

[F8](i) . . . . . .

[[F9](ii) in sub-paragraph (b), after "Article 21" insert "or regulation 64(6) of the 2012 Regulations"; and**]**

[F10](b) . . . . . .

[F11](5) . . . . . .

[F12](6) . . . . . .

Textual Amendments

F6 Sch. 8 para. 16(2)(a)-(d) omitted (31.12.2020 immediately before IP completion day) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 194(d)(i)**

F7 Sch. 8 para. 16(3) omitted (31.12.2020 immediately before IP completion day) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 194(d)(ii)**

F8 Sch. 8 para. 16(4)(a)(i) omitted (31.12.2020 immediately before IP completion day) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 194(d)(iii)**

F9 Sch. 8 para. 16(4)(a)(ii) substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 194(d)(iv)**

F10 Sch. 8 para. 16(4)(b) omitted (31.12.2020 immediately before IP completion day) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 194(d)(v)**

F11 Sch. 8 para. 16(5) omitted (31.12.2020 immediately before IP completion day) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 194(d)(vi)**

F12 Sch. 8 para. 16(6) omitted (31.12.2020 immediately before IP completion day) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 194(d)(vii)**

Commencement Information

I16 Sch. 8 para. 16 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Marginal Citations

M22 S.I. 2018/345.

Changes to legislation:
There are currently no known outstanding effects for the The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019, SCHEDULE 8.