SCHEDULE 8

Consequential provision

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)(**1**)—

(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.".

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

4. In article 5(1) of the Prescription Only Medicines (Human Use) Order 1997 (exempt medicinal products)(**2**), insert "UK" before "marketing authorisation".

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

5.—(1) The Medicines (Aristolochia and Mu Tong etc) (Prohibition) Order 2001(**3**) is amended as follows.

(2) In article 1 (citation, commencement and interpretation)(**4**)—

(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)(**5**)—

(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

(**1**) S.I. 1977/670. Article 2 was amended by S.I. 1990/2487, 1997/856, 2008/548 and 2012/1809.
(**2**) S.I. 1997/1830. Article 5(1) was amended by S.I. 2012/1916.
(**3**) S.I. 2001/1841.
(**4**) Article 1 was amended by S.I. 2008/548 and 2012/1809.
(**5**) Article 4 was amended by S.I. 2008/548 and 2012/1916.

(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".

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

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

(2) In article 1 (citation, commencement and interpretation)(**7**)—

(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)(**8**)—

(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".

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

7. In regulation 1(2) of the Unlicensed Medicinal Products for Human Use (Transmissible Spongiform Encephalopathies) (Safety) Regulations 2003 (citation, commencement and interpretation)(**9**), in the definition of "unlicensed product"—

(a) in paragraph (a) for "marketing authorization" substitute "UK marketing authorisation"; and

(b) omit paragraphs (a)(ii) and (d).

Amendment of the Blood Safety and Quality Regulations 2005

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

"(10A) Paragraph 7.1 is to be read as if reference to "Directive 2003/94/EC" were to "the Good Manufacturing Practice Directive, within the meaning of regulation 8(1) of the Human Medicines Regulations 2012.".

(**6**) S.I. 2002/3170.
(**7**) Article 1 was amended by S.I. 2008/548 and 2012/1809.
(**8**) Article 3 was amended by S.I. 2008/548 and 2012/1916.
(**9**) S.I. 2003/1680. Regulation 2(1) has been previously amended by S.I. 2004/3224, 2005/2750 and 2754 and 2012/1916.
(**10**) 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)(**11**) for "Directive" to the end substitute "regulation 2(1) of the Human Medicines Regulations 2012".

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(**12**) is amended as follows.

(2) In article 1 (citation, commencement and interpretation)(**13**)—

(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)(**14**)—

(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".

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(**15**) 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.

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)(**16**), at the end insert—

"; or

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

(**11**) S.I. 2007/2785. Regulation 3(1)(a) was substituted by S.I. 2018/352.
(**12**) S.I. 2008/548.
(**13**) Article 1 was amended by S.I. 2012/1809.
(**14**) Article 3 was amended by S.I. 2012/1916.
(**15**) S.I. 2013/349.
(**16**) 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(**17**) 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".

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)(**18**), at the end insert—

"; or

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

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(**19**)—

(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".

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

16.—(1) The Branded Health Service Medicines (Costs) Regulations 2018(**20**) are amended as follows.

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

(a) in the definition of "marketing authorisation" insert "UK" before "marketing" and re-insert the definition at the appropriate place;

(b) in the definition of "marketing authorisation holder" insert "UK" before "marketing" in and re-insert the definition at the appropriate place;

(c) omit the definition of "parallel distributed presentation";

(d) in paragraph (b) of the definition of "relevant medicine" insert "UK" before "marketing authorisation"; and

(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".

(**17**) S.I. 2015/895.
(**18**) S.R. 2015 No. 339.
(**19**) S.I. 2018/677.
(**20**) S.I. 2018/345.

(3) In regulation 3 (payment scheme)—

(a) in paragraph (3)(a), insert "UK" before "marketing authorisation holder";

(b) omit paragraph (4)(c).

(4) In regulation 9 (new presentation)—

(a) in paragraph (10)—

(i) in sub-paragraph (a), insert at the beginning "in relation to a product in respect of which there is a converted EU marketing authorisation",

(ii) in sub-paragraph (b), for "Article 21" to the end substitute "regulation 64(6) of the 2012 Regulations"; and

(b) in paragraph (12), insert before the definition of "licensing authority"—

""converted EU marketing authorisation" has the meaning given in paragraph 6(1) and (2) of Schedule 33A to the 2012 Regulations;".

(5) In regulation 21 (sales report), omit paragraph (1)(h).

(6) In regulation 22 (presentation report), omit sub-paragraph (h).