Draft Regulations laid before Parliament under paragraph 1(1) of Schedule 7 to the European Union (Withdrawal) Act 2018, for approval by resolution of each House of Parliament.

D R A F T S T A T U T O R Y I N S T R U M E N T S

2020 No. XXX

EXITING THE EUROPEAN UNION

INTERNATIONAL DEVELOPMENT

MEDICINES

TRADE

The Prevention of Trade Diversion (Key Medicines) (EU Exit) Regulations 2020

Made - - - - ***

Coming into force in accordance with regulation 1

The Secretary of State makes these Regulations in exercise of the powers conferred by section 8(1) of, and paragraph 21 of Schedule 7 to, the European Union (Withdrawal) Act 2018(**a**).

In accordance with paragraph 1(1) of Schedule 7 to that Act, a draft of this instrument was laid before and approved by a resolution of each House of Parliament.

PART 1

Introduction

Citation and commencement

1. These Regulations may be cited as the Prevention of Trade Diversion (Key Medicines) (EU Exit) Regulations 2020 and come into force on IP completion day.

(**a**) 2018 c. 16.

PART 2

Amendments to retained direct EU legislation: Great Britain

Amendment of Regulation (EU) 2016/793 of the European Parliament and of the Council to avoid trade diversion into the European Union of certain key medicines

2.—(1) Regulation (EU) 2016/793 of the European Parliament and of the Council of 11 May 2016 to avoid trade diversion into the European Union of certain key medicines, as it applies in Great Britain on and after IP completion day, is amended as follows.

(2) In Article 1 in paragraph 2—

(a) in point (a), for "Commission", substitute "Secretary of State";

(b) after point (c), insert—

"(d) 'customs tariff' is the system provided for in regulations made under section 8 of the Taxation (Cross-border Trade) Act 2018(**a**).".

(3) In Article 2—

(a) in paragraph 1—

(i) for "the Union", substitute "Great Britain";

(ii) for "re-export", substitute "export";

(iii) for "placing under suspensive procedures or placing in a free zone or free warehouse", substitute "or a special Customs procedure";

(b) in paragraph 2—

(i) in points (a) and (b), for "re-export", substitute "export of the tiered-priced products";

(ii) in point (b), for "customs warehouse procedure or in a free zone or free warehouse", substitute "storage procedure";

(c) after paragraph 2, insert—

"3. In this Article—

(a) 'special Customs procedure' has the meaning given by section 3(4) of the Taxation (Cross-border Trade) Act 2018;

(b) 'storage procedure' has the meaning given by paragraph 2(1) of Schedule 2 to the Taxation (Cross-border Trade) Act 2018.".

(4) In Article 4—

(a) in paragraph 1—

(i) for "Commission", substitute "Secretary of State";

(ii) at the end insert—

"Applications must be sent to the Department for International Trade, 3 Whitehall Place, London SW1A 2AW.";

(b) in paragraph 2—

(i) for "Commission", in each place where it occurs, substitute "Secretary of State";

(ii) for point (d), substitute—

"(d) the goods classification code for the goods based on the equivalent goods classification code that is in the customs tariff, as it applies at the time of the application, to identify unambiguously the goods concerned; and";

(iii) in point (e), for "the Union", substitute "Great Britain";

(**a**) 2018 c. 22.

(c) for paragraph 3 substitute—

"3. The Secretary of State must determine whether a product, which is the subject of an application under paragraph 2 or a notification under paragraph 6, fulfils the requirements of this Regulation to qualify as a tiered-priced product. The Secretary of State must inform the applicant of the decision before the end of the period of 15 days, beginning with the date on which the decision was made.";

(d) after paragraph 3, insert—

"3A. The Secretary of State must, from time to time, make regulations to amend Annex I to add any product to the list set out in that Annex if the Secretary of State determines, under paragraph 3, that that product fulfils the requirements of this Regulation to qualify as a tiered-priced product.";

(e) in paragraphs 4 and 5, for "Commission", substitute "Secretary of State";

(f) omit paragraph 7;

(g) for paragraph 8, substitute—

"8. The Secretary of State may by regulations amend Annexes II, III and IV to revise—

(a) the list of diseases,

(b) the countries of destination covered by this Regulation, or

(c) the formulae used to identify tiered-priced products,

if the Secretary of State considers that it is necessary to do so in light of the experience gained from the application of this Regulation or in order to respond to a health crisis.".

(5) For Article 5, substitute—

"Article 5

1. The Secretary of State must from time to time—

(a) carry out a review of this Regulation;

(b) set out the conclusions of the review in a report; and

(c) publish the report.

2. The report must in particular—

(a) set out the use of the powers to make regulations at Article 4(3A), Article 4(8), Article 7 and Article 8; and

(b) set out any other matters that the Secretary of State considers relevant in respect of the powers referred to at subparagraph (a).

3. The first report must be published before the end of the period of five years beginning with the date on which the Prevention of Trade Diversion (Key Medicines) (EU Exit) Regulations 2020 come into force.".

(6) Omit Article 6.

(7) For Article 7, substitute—

"Article 7

1. For products listed as tiered-priced products in Annex I, an applicant must submit information to the Secretary of State relating to any change which has occurred since the product was added to that list with respect to the information provided in the application specified in Article 4(2). Such information must be sent to the address provided at Article 4(1).

2. The Secretary of State must, from time to time and upon receipt of information under paragraph 1, review whether a product listed as a tiered-priced product in Annex I fulfils the requirements of this Regulation to qualify as a tiered-priced product.

3. The Secretary of State may make regulations to amend the list of tiered-priced products in Annex I to remove any product from that list if the Secretary of State determines, under paragraph 2, that that product no longer fulfils the requirements of this Regulation to qualify as a tiered-priced product.".

(8) For Article 8, substitute—

"Article 8

The Secretary of State may by regulations make such provision regarding marking, labelling or other identification requirements for tiered-priced products listed in Annex I as the Secretary of State considers appropriate.".

(9) In Article 9—

(a) in paragraph 1—

(i) for "the Union", substitute "Great Britain";

(ii) for "competent authorities", substitute "competent authority";

(b) in paragraph 3—

(i) omit "in the Member State concerned";

(ii) for "national provisions on", substitute "the law relating to".

(10) In Article 10—

(a) in paragraph 1, in the first sentence, after "national legislation", insert "(as to which, see Part 11 of the Customs and Excise Management Act 1979(**a**))";

(b) omit paragraph 3.

(11) For Article 11, substitute—

"Article 11

1. This Regulation does not apply to non-commercial goods or personal gifts within the accompanied baggage of a qualifying traveller if at the time of import a relief from import duty is available in respect of the goods or gifts(**b**).

2. In this Article, "non-commercial goods", "personal gifts", "accompanied baggage" and "qualifying traveller" have the meaning given to them by regulation 2 of the Customs (Import Duty) (EU Exit) Regulations 2018(**c**).".

(12) Omit Article 12.

(13) In Article 13, for paragraph 1, substitute—

"1. The application of this Regulation does not affect procedures laid down in the Human Medicines Regulations 2012(**d**).".

(14) In Article 14, omit the second sentence.

(15) After Article 15—

(a) omit "This Regulation shall be binding in its entirety and directly applicable in all Member States.";

(b) insert—

"Article 16

1. Regulations made under a provision specified in paragraph 2—

(a) are to be made by statutory instrument;

(**a**) 1979 c.2

(**b**) See section 19 of the Taxation (Cross-border) Trade Act 2018 and regulations made under that section concerning reliefs from liability to import duty.

(**c**) S.I. 2018/1248.

(**d**) S.I. 2012/1916; relevant amendments were made by S.I. 2019/775.

(b) may make different provision for different purposes and different areas;

(c) may include incidental, supplemental, consequential, transitional, transitory or saving provisions, including consequential amendments to these Regulations.

2. The provisions specified in this paragraph are—

(a) Article 4(3A);

(b) Article 4(8);

(c) Article 7;

(d) Article 8.

3. A statutory instrument containing regulations made under any of the provisions specified in paragraph 2 is subject to annulment in pursuance of a resolution of either House of Parliament.".

(16) In Annex 1, in the table—

(a) in the sixth column heading, for "CN/TARIC code ([1])", substitute "Goods classification code under the customs tariff";

(b) in the sixth column, every code number is to be read as the equivalent goods classification code number that is in the customs tariff on the day on which these Regulations come into force.

(17) Omit Annexes 5 and 7.

Signed by authority of the Secretary of State

Name
Title
Department for International Trade

Date

EXPLANATORY NOTE

(This note is not part of the Regulations)

Regulation (EU) 2016/793 of the European Parliament and of the Council of 11 May 2016 to avoid trade diversion into the European Union of certain key medicines, as that Regulation applies in Great Britain at the end of the transition period, is amended by these Regulations.

These Regulations are made in exercise of the powers in section 8(1) of, and paragraph 21 of Schedule 7 to, the European Union (Withdrawal) Act 2018 (c. 16) (the "Act") in order to address failures of retained EU law to operate effectively and other deficiencies (in particular under section 8(2)(a), (b), (c), (d), and (g) of that Act) arising from the withdrawal of the United Kingdom from the European Union.

Regulation (EU) 2016/793 controls the import of certain key medicines (called tiered-priced products) into the European Union. These are medicines which are destined for certain developing countries and sold at reduced prices. These Regulations make amendments to Regulation (EU) 2016/793 as it has effect in Great Britain after IP completion day in order to enable the continued control of the importation of these products into Great Britain.

In these Regulations, the function of the Commission to adopt delegated acts to amend Annex I (List of tiered-priced products) of Regulation (EU) 2016/793 has been replaced by a power for the Secretary of State to add products to Annex I and a power for the Secretary of State to remove products from Annex I by regulations (see regulations 2(4)(d) and 2(7)).

In regulation 2(4)(g), the function of the Commission to adopt delegated acts to amend Annex II (Countries of destination), Annex III (Percentages referred to in Article 3) and Annex IV (Scope of diseases) of Regulation (EU) 2016/793 has been replaced by a power for the Secretary of State to amend these Annexes by regulations.

In regulation 2(5), the requirement for the Commission to draw up a report after 5 years in respect of the delegation of power to the Commission has been replaced by a requirement for the Secretary of State to carry out a review of Regulation (EU) 2016/793 and publish a report which, in particular, sets out the use of the powers to make regulations at Article 4(3A), Article 4(8), Article 7 and Article 8 and sets out any other matters the Secretary of State considers relevant in respect of these powers. The power (in Article 5(3)) for the European Parliament or the Council to revoke the delegation of powers conferred to the Commission under Article 4(3) and (8) in Regulation (EU) 2016/793 is omitted (see regulation 2(5)).

In regulation 2(8), the requirement for a logo (as set out in Article 8 of, and Annex V to, Regulation (EU) 2016/793) for tiered-priced products, is replaced by a power for the Secretary of State to make regulations containing such provision regarding marking, labelling or other identification requirements for tiered-priced products as the Secretary of State considers appropriate.

An impact assessment has not been produced for this instrument as no, or no significant, impact on the private, voluntary or public sector is foreseen.

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