EXPLANATORY MEMORANDUM TO

THE PREVENTION OF TRADE DIVERSION (KEY MEDICINES) (EU EXIT) REGULATIONS 2020

2020 No. [XXXX]

1. Introduction

1.1 This explanatory memorandum has been prepared by the Department for International Trade and is laid before Parliament by Command of Her Majesty.

1.2 This memorandum contains information for the Joint Committee on Statutory Instruments.

2. Purpose of the instrument

2.1 This instrument is made under section 8 of and paragraph 21 of Schedule 7 to the EU (Withdrawal) Act 2018 ("the EUWA"). It makes amendments to the retained domestic version of Regulation (EU) 2016/793 by removing inappropriate references to the EU, EU legislation and the European Commission that will no longer apply to Great Britain at the end of the Implementation Period.

Explanations

What did any relevant EU law do before exit day?

2.2 Regulation (EU) 2016/793:

a. establishes a system controlling the import of certain medicines into the European Union, called "tiered-priced products", that are destined for developing countries and sold to these countries at heavily reduced prices to avoid trade diversion;

b. contains criteria which medicines must fulfil in order to be on the list of tiered-priced products, including:

- countries of destination,
- pricing formulae limiting the price of the product,
- the diseases that the medicines must prevent, diagnose or treat,
- product labelling requirements;

c. establishes a process for the Commission to amend the list of tiered-priced products and to amend some of the criteria which products must fulfil in order to be listed as tiered-priced products (the countries of destination, pricing formulae and the diseases that the medicines must prevent, diagnose or treat);

d. provides a power for customs authorities to suspend the release of or detain products for which there is sufficient information available for customs authorities to consider that the product concerned is a tiered-priced product; and

e. provides functions for the competent authorities of members states to:

- determine whether products seized by customs authorities are tiered-priced products,
- ensure that the product determined to be tiered-priced products are seized and disposed of in accordance with national legislation,

- inform the Commission of all decisions adopted pursuant to Regulation (EU) 2016/793.

Why is it being changed?

2.3 Regulation (EU) 2016/793 contains a number of references to the European Union, the Commission and EU laws that will no longer be appropriate at the end of the Implementation Period. These Regulations are required to amend or remove these inappropriate references in the retained domestic version of Regulation (EU) 2016/793 which will apply in Great Britain and replace them with references to Great Britain or to UK legislation as appropriate.

What will it now do?

2.4 The instrument corrects the deficiencies as set out in paragraph 2.1 in order to:

a. maintain the existing controls on the import of tiered-priced products listed in Regulation (EU) 2016/793 in Great Britain;

b. transfer the Commission's functions to amend the list of tiered-priced products and to amend criteria for products to remain on that list (list of diseases, list of countries of destination and pricing formulae) to the Secretary of State to amend by making regulations;

c. maintain functions of the competent authority to determine whether products detained by the customs authorities are tiered-priced products and to ensure that such products are seized and disposed of in accordance with national legislation; and

d. replace the requirement for tiered-priced products, packaging and connected documents to affix an EU logo with a power for the Secretary of State to make regulations providing for marking, labelling or other identification requirements for tiered-priced products, as the Secretary of State considers appropriate.

3. Matters of special interest to Parliament

Matters of special interest to the Joint Committee on Statutory Instruments

3.1 This instrument includes powers for the Secretary of State to legislate by negative procedure.

Matters relevant to Standing Orders Nos. 83P and 83T of the Standing Orders of the House of Commons relating to Public Business (English Votes for English Laws)

3.2 The territorial application of this instrument includes Scotland.

4. Extent and Territorial Application

4.1 The territorial extent of this instrument is the whole of the United Kingdom (England and Wales, Scotland and Northern Ireland).

4.2 The territorial application of this instrument is England, Wales and Scotland.

4.3 The retained domestic version of Regulation (EU) 2016/793 is incorporated into domestic law under section 8 of the European Union (Withdrawal) Act 2018 save insofar as it applies to Northern Ireland for the purposes of the Ireland/Northern Ireland Protocol. Accordingly, this instrument will be of no practical application in

Northern Ireland as the Ireland/Northern Ireland Protocol instead applies Regulation (EU) 2016/793 in Northern Ireland.

5. European Convention on Human Rights

5.1 The Minister for International Trade, Greg Hands, has made the following statement regarding Human Rights:

"In my view the provisions of the Prevention of Trade Diversion (Key Medicines) (EU Exit) Regulations 2020 are compatible with the Convention rights."

6. Legislative Context

6.1 The import control on tiered-priced products has been in place since Council Regulation (EC) 2003/953 came into force. Regulation (EU) 2016/793 is a consolidation Regulation of Regulation (EC) 2003/953 and subsequent amendments to that Regulation.

6.2 Section 3 EUWA provides that EU Regulations and tertiary Regulations continue to form part of domestic law on or after the Implementation Period and these also form part of retained EU law.

6.3 Section 8 EUWA provides that a Minister of the Crown may by regulations make such provision as the Minister considers appropriate to prevent, remedy or mitigate (a) any failure of retained EU law to operate effectively; or (b) any other deficiency in retained EU law arising from the withdrawal of the United Kingdom from the EU. This includes power to make supplementary and consequential provisions (including re-stating EU law in a clearer way in relation to making reference to the national legislation provisions that apply to powers of seizure and disposal of tiered-priced products) (set out at Schedule 7 paragraph 21(b) of the EUWA).

6.4 This instrument relies on the power at section 8 and Schedule 7 paragraph 21(b) EUWA to amend Regulation (EU) 2016/793 to ensure it operates effectively at the end of the Implementation Period. The instrument transfers the functions of the Commission to amend the list of tiered-priced products, countries of destination, list of diseases and the price calculation formulae to the Secretary of State to amend by regulations. The instrument also contains an additional power for the Secretary of State to make regulations providing for the marking, labelling or other identification requirements for tiered-priced products, as the Secretary of State considers appropriate. This power replaces the requirement for a logo to be affixed to any packaging, product or associated document.

6.5 Existing UK legislation, the Customs and Excise Management Act 1979 provides for seizure and disposal of tiered-price products imported contrary to Regulation (EU) 2016/793 (see Part 11).

6.6 The Medicines Healthcare products Regulatory Agency (MHRA), an executive agency of the Department of Health and Social Care, carries out the functions of the competent authority in the United Kingdom in relevant EU provisions in the area of human medicines under regulation 6 of the Human Medicines Regulation 2012. Its functions include the functions of the competent authority under Regulation (EU) 2016/793. After the Implementation Period, this instrument provides for the Secretary of State to continue to perform the functions of the competent authority in Regulation 2016/793, save the function of reporting its decisions to the Commission (Article 10(3)) which is omitted.

6.7 Regulation (EU) 2016/793 continues to be directly applicable to and in the United Kingdom in respect of Northern Ireland by virtue of section 7A of the EUWA as it is listed in Annex 2 of the Protocol on Ireland/Northern Ireland to the Withdrawal Agreement.

7. Policy background

What is being done and why?

7.1 This instrument amends the retained domestic version of Regulation (EU) 2016/793 as it applies in Great Britain at the end of the Implementation Period to correct technical deficiencies.

7.2 In 2001, the Commission adopted a communication to the European Parliament and to the Council on accelerated action targeted at major communicable diseases within the context of poverty reduction, according to which the Commission was instructed to establish a global tiered pricing system for key pharmaceuticals for the prevention, diagnosis and treatment of HIV/AIDS, tuberculosis and malaria and related diseases for the poorest developing countries and to prevent product diversion of these products to other markets by ensuring that effective safeguards were in place.

7.3 Many of the poorest developing countries are in urgent need of access to affordable essential medicines for the treatment of communicable diseases. Those countries are heavily dependent on imports of medicines as local manufacturing is limited.

7.4 Price segmentation between developing and developed countries is necessary to ensure that the poorest developing countries have access to essential pharmaceutical products at heavily reduced prices.

7.5 There is a need to encourage pharmaceutical manufacturers to produce large volumes of pharmaceutical products at reduced prices by ensuring that the products do not enter developed countries' markets. Regulation 2016/793 aims to ensure that the reduced-price pharmaceutical products remain on the developing countries' markets by identifying the products, countries and diseases covered by Regulation (EU) 2016/793 and preventing the products from being imported into the European Union.

7.6 This instrument is not retaining the requirement in Regulation 2016/793 that tiered-priced products must have an EU logo affixed to the product, packaging and any connected documents. Retaining the requirement to affix the EU logo would be inappropriate given the potential for future divergence in the list of tiered-priced products between the EU and the UK after the Implementation Period. Instead, this requirement will be replaced with a power for the Secretary of State to make regulations, as the Secretary of State considers appropriate. New labelling or other identifications requirements may therefore be provided for in future regulations further to consultation with stakeholders.

7.7 This instrument will come into force at the end of the Implementation Period.

8. European Union (Withdrawal) Act/Withdrawal of the United Kingdom from the European Union

8.1 This instrument is being made using the power in section 8 of the European Union (Withdrawal) Act 2018 in order to address failures of retained EU law to operate effectively or other deficiencies arising after the end of the Implementation Period. This instrument is also made under the power in the Withdrawal Act 2018 in

paragraph 21 of Schedule 7 to make supplementary and consequential provisions (including re-stating EU law in a clearer way in relation to making reference to the national legislation provisions that apply to powers of seizure and disposal of tiered-priced products). In accordance with the requirements of that Act the Minister has made the relevant statements as detailed in Part 2 of the Annex to this Explanatory Memorandum.

9. Consolidation

9.1 None.

10. Consultation outcome

10.1 There is no requirement for a formal consultation. This instrument implements the existing control of importation of tiered-priced medicines that operates under EU law.

11. Guidance

11.1 The Department for International Trade does not propose to issue any guidance in relation to this statutory instrument currently.

12. Impact

12.1 There is no, or no significant, impact on business, charities or voluntary bodies.

12.2 There is no, or no significant, impact on the public sector.

12.3 An Impact Assessment has not been prepared for this instrument because it amends existing law applicable in the United Kingdom in order for that legislation to continue to function effectively at the end of the Implementation Period. This instrument omits the requirement for tiered-priced products to affix a logo to the product, packaging and any connected documents. However, no impact to business is foreseen as a result of this change, as no change in packaging is required. There is also a minor change of procedure for manufacturers and exporters as a result of amendments made by this instrument: manufacturers or exporters were required to apply to the Commission to have a product added to Annex I or to notify the Commission of a relevant change to a product listed at Annex I; they are now required to apply to or notify the Secretary of State instead. No immediate or significant impact is foreseen as a result of this change of procedure.

12.4 This instrument does not alter the law as it applies in Northern Ireland under the Regulation (EU) 2016/793.

13. Regulating small business

13.1 This legislation does not apply to activities that are undertaken by small business.

14. Monitoring & review

14.1 Regulation (EU) 2016/793 confers the power to adopt delegated acts to the Commission for a period of five years which is tacitly extended for periods of identical duration thereafter. There is a requirement for the Commission to draw up a report before the expiry of the five-year period in respect of the delegation of power. This has been replaced by a requirement for the Secretary of State to carry out a review of Regulation (EU) 2016/793, as amended by this instrument, and publish a report which, in particular, sets out the use of the powers within this instrument to

make regulations and sets out any other matters the Secretary of State considers relevant in respect of these powers. The first report must be published before the end of the period of five years beginning with the date on which this instrument comes into force.

14.2 (EU) 2016/793 contains a requirement for manufacturers and exports of tiered-priced products to submit annual sales reports to the Commission in order to remain on the list of such products. There is a requirement for the Commission to monitor on an annual basis the volumes of exports of tiered-priced products and exported to the countries of destination based on this information. The Commission is then required to report biennially to the European Parliament and to the Council on the volumes exported under tiered prices. These requirements are omitted by this instrument. This instrument provides for the Secretary of State to review, from time to time, whether a product listed as a tiered-priced product fulfils the requirements of Regulation (EU) 2016/793.

14.3 This instrument omits the requirement for the competent authority to inform the Commission of all decisions adopted pursuant to Regulation (EU) 2016/793. Any detentions of the prohibited tiered-priced products will continue to be advised to the competent authority. Information on imports and on Border Force activity will be collected, reviewed and, where appropriate, made public by the Government as part of standard procedure.

14.4 Regulation 2016/793 contains provision for the Commission to amend the list of countries of destination, the list of diseases and the price calculation formulae in light of the experience gained by the application of Regulation 2016/793. This instrument transfers this power to the Secretary of State to amend these criteria if the Secretary of State considers it necessary to do so, having regard to the application of this Regulation or in order to respond to a health crisis. This instrument also includes a power for the Secretary of State to remove products from the list of products at Annex I, upon a product no longer meeting the requirements to remain on the list.

14.5 As this instrument is made under the European Union Withdrawal Act 2018, no review clause is required.

15. Contact

15.1 Rachel Ademosu at the Department for International Trade Telephone: 02072150784 or email: importcontrols@trade.gov.uk can be contacted with any queries regarding the instrument.

15.2 Ada Igboemeka at the Department for International Trade can confirm that this Explanatory Memorandum meets the required standard.

15.3 Greg Hands, Minister at the Department for International Trade can confirm that this Explanatory Memorandum meets the required standard.

Annex

Statements under the European Union (Withdrawal) Act 2018

Part 1

Table of Statements under the 2018 Act

This table sets out the statements that may be required under the 2018 Act.

Statement	Where the requirement sits	To whom it applies	What it requires
Sifting	Paragraphs 3(3), 3(7) and 17(3) and 17(7) of Schedule 7	Ministers of the Crown exercising clauses 8(1), 9 and 23(1) to make a Negative SI	Explain why the instrument should be subject to the negative procedure and, if applicable, why they disagree with the recommendation(s) of the SLSC/ESIC
Appropriate-ness	Sub-paragraph (2) of paragraph 28, Schedule 7	Ministers of the Crown exercising clauses 8(1), 9 and 23(1) or jointly exercising powers in Schedule 2	A statement that the SI does no more than is appropriate.
Good Reasons	Sub-paragraph (3) of paragraph 28, Schedule 7	Ministers of the Crown exercising clauses 8(1), 9 and 23(1) or jointly exercising powers in Schedule 2	Explain the good reasons for making the instrument and that what is being done is a reasonable course of action.
Equalities	Sub-paragraphs (4) and (5) of paragraph 28, Schedule 7	Ministers of the Crown exercising clauses 8(1), 9 and 23(1) or jointly exercising powers in Schedule 2	Explain what, if any, amendment, repeals or revocations are being made to the Equalities Acts 2006 and 2010 and legislation made under them. State that the Minister has had due regard to the need to eliminate discrimination and other conduct prohibited under the Equality Act 2010.
Explanation	Sub-paragraph (6) of	Ministers of the Crown	Explain the instrument, identify the

s	paragraph 28, Schedule 7	exercising clauses 8(1), 9 and 23(1) or jointly exercising powers in Schedule 2 In addition to the statutory obligation the Government has made a political commitment to include these statements alongside all EUWA SIs	relevant law before exit day, explain the instrument's effect on retained EU law and give information about the purpose of the instrument, e.g., whether minor or technical changes only are intended to the EU retained law.
Criminal offences	Sub-paragraphs (3) and (7) of paragraph 28, Schedule 7	Ministers of the Crown exercising clauses 8(1), 9, and 23(1) or jointly exercising powers in Schedule 2 to create a criminal offence	Set out the 'good reasons' for creating a criminal offence, and the penalty attached.
Sub-delegation	Paragraph 30, Schedule 7	Ministers of the Crown exercising clauses 10(1), 12 and part 1 of Schedule 4 to create a legislative power exercisable not by a Minister of the Crown or a Devolved Authority by Statutory Instrument.	State why it is appropriate to create such a sub-delegated power.
Urgency	Paragraph 34, Schedule 7	Ministers of the Crown using the urgent procedure in paragraphs 4 or 14, Sch 7.	Statement of the reasons for the Minister's opinion that the SI is urgent.
Explanations where amending regulations under 2(2) ECA 1972	Paragraph 13, Schedule 8	Anybody making an SI after exit day under powers outside the European Union (Withdrawal) Act 2018 which modifies subordinate legislation made under s.2(2) ECA	Statement explaining the good reasons for modifying the instrument made under s.2(2) ECA, identifying the relevant law before exit day, and explaining the instrument's effect on retained EU law.
Scrutiny statement where	Paragraph 16, Schedule 8	Anybody making an SI after exit day under powers outside the	Statement setting out: a) the steps which the relevant authority has taken to make the

amending regulations under 2(2) ECA 1972		European Union (Withdrawal) Act 2018 which modifies subordinate legislation made under s.2(2) ECA	draft instrument published in accordance with paragraph 16(2), Schedule 8 available to each House of Parliament, b) containing information about the relevant authority's response to— (i) any recommendations made by a committee of either House of Parliament about the published draft instrument, and (ii) any other representations made to the relevant authority about the published draft instrument, and, c) containing any other information that the relevant authority considers appropriate in relation to the scrutiny of the instrument or draft instrument which is to be laid.

Part 2

Statements required when using enabling powers under the European Union (Withdrawal) 2018 Act

1. Appropriateness statement

1.1 In my view the Prevention of Trade Diversion (Key Medicines) (EU Exit) Regulations 2020 do no more than is appropriate. This is the case because UK left the EU on 31 January 2020 and is therefore no longer be a Member State of the European Union. Provisions designed in the context of EU membership need to be adapted accordingly, while doing no more than maintaining existing policy.

2. Good reasons

2.1 In my view there are good reasons for the provisions in this instrument, and I have concluded they are a reasonable course of action. These are that regulations would otherwise contain a number of references to the European Union, the Commission and EU laws that would no longer be appropriate in the UK after exit. These reasons are explained further in sections 2.4, 7.1 and 8.1 of the explanatory memorandum.

3. Equalities

3.1 The instrument does not amend, repeal or revoke a provision or provisions in the Equality Act 2006 or the Equality Act 2010 or subordinate legislation made under those Acts.

"In relation to the instrument, I, Greg Hands, have due regard to the need to eliminate discrimination, harassment, victimisation and any other conduct that is prohibited by or under the Equality Act 2010."

4. Explanations

4.1 The explanations statement has been made in section 2 of the main body of the explanatory memorandum.