

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 (codification)

Article 1	(1) This Regulation lays down: (a) the criteria for establishing...
Article 2	(1) The importation into the Union of tiered-priced products for...
Article 3	The tiered price referred to in Article 4(2)(b) shall, at...
Article 4	(1) In order for products to benefit from this Regulation,...
Article 5	(1) The power to adopt delegated acts is conferred on...
Article 6	(1) Delegated acts adopted under this Article shall enter into...
Article 7	A product approved as a tiered-priced product and listed in...
Article 8	A permanent logo, as set out in Annex V, shall...
Article 9	(1) Where there is reason to suspect that, contrary to...
Article 10	(1) If products suspended for release or detained by customs...
Article 11	This Regulation shall not apply to goods of a non-commercial...
Article 12	(1) The Commission shall monitor on an annual basis the...
Article 13	(1) The application of this Regulation shall in no circumstances...
Article 14	Regulation (EC) No 953/2003 is repealed. References to the repealed...
Article 15	This Regulation shall enter into force on the twentieth day...
	Signature

ANNEX I

LIST OF TIERED-PRICED PRODUCTS

ANNEX II

COUNTRIES OF DESTINATION

Afghanistan
Angola
Armenia
Azerbaijan
Bangladesh
Benin
Bhutan
Botswana
Burkina Faso
Burundi
Cambodia
Cameroon
Cape Verde
Central African Republic
Chad
China
Comoros

Changes to legislation: There are outstanding changes not yet made to Regulation (EU) 2016/793 of the European Parliament and of the Council. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes

Congo
Côte d'Ivoire
Democratic Republic of the Congo
Djibouti
Equatorial Guinea
Eritrea
Ethiopia
Gambia
Ghana
Guinea
Guinea-Bissau
Haiti
Honduras
India
Indonesia
Kenya
Kiribati
Kyrgyzstan
Laos
Lesotho
Liberia
Madagascar
Malawi
Maldives
Mali
Mauritania
Moldova
Mongolia
Mozambique
Myanmar/Burma
Namibia
Nepal
Nicaragua
Niger
Nigeria
North Korea
Pakistan
Rwanda
Samoa
São Tomé and Príncipe
Senegal
Sierra Leone
Solomon Islands
Somalia
South Africa
Sudan
Swaziland
Tajikistan
Tanzania
Timor-Leste
Togo
Turkmenistan
Tuvalu

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Uganda
Vanuatu
Vietnam
Yemen
Zambia
Zimbabwe

ANNEX III

PERCENTAGES REFERRED TO IN ARTICLE 3

Percentage referred to in Article 3(a): 25 %
Percentage referred to in Article 3(b): 15 %

ANNEX IV

SCOPE OF DISEASES

HIV/AIDS, malaria, tuberculosis and related opportunistic diseases

ANNEX V

LOGO

The winged staff of Aesculapius with a coiled serpent, in...

ANNEX VI

REPEALED REGULATION WITH LIST OF ITS SUCCESSIVE AMENDMENTS

ANNEX VII

CORRELATION TABLE

Changes to legislation: There are outstanding changes not yet made to Regulation (EU) 2016/793 of the European Parliament and of the Council. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) [View outstanding changes](#)

- (1) Position of the European Parliament of 9 March 2016 (not yet published in the Official Journal) and decision of the Council of 11 April 2016.
- (2) Council Regulation (EC) No 953/2003 of 26 May 2003 to avoid trade diversion into the European Union of certain key medicines ([OJ L 135, 3.6.2003, p. 5](#)).
- (3) See Annex VI.
- (4) Regulation (EU) No 608/2013 of the European Parliament and of the Council of 12 June 2013 concerning customs enforcement of intellectual property rights and repealing Council Regulation (EC) No 1383/2003 ([OJ L 181, 29.6.2013, p. 15](#)).

Changes to legislation:

There are outstanding changes not yet made to Regulation (EU) 2016/793 of the European Parliament and of the Council. Any changes that have already been made to the legislation appear in the content and are referenced with annotations.

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Changes and effects yet to be applied to :

- Annex 1 modified by S.I. 2020/1354 reg. 2(16)(b)
- Annex 1 words substituted by S.I. 2020/1354 reg. 2(16)(a)
- Annex 5 omitted by S.I. 2020/1354 reg. 2(17)
- Annex 7 omitted by S.I. 2020/1354 reg. 2(17)
- Art. 2(1) word substituted by S.I. 2020/1354 reg. 2(3)(a)(ii)
- Art. 2(1) words substituted by S.I. 2020/1354 reg. 2(3)(a)(i)
- Art. 2(1) words substituted by S.I. 2020/1354 reg. 2(3)(a)(iii)
- Art. 4(1) words inserted by S.I. 2020/1354 reg. 2(4)(a)(ii)
- Art. 4(1) words substituted by S.I. 2020/1354 reg. 2(4)(a)(i)
- Art. 4(1) words substituted by S.I. 2023/424 Sch. para. 80
- Art. 4(2) words substituted by S.I. 2020/1354 reg. 2(4)(b)(i)
- Art. 4(3) substituted by S.I. 2020/1354 reg. 2(4)(c)
- Art. 4(4) words substituted by S.I. 2020/1354 reg. 2(4)(e)
- Art. 4(5) words substituted by S.I. 2020/1354 reg. 2(4)(e)
- Art. 4(7) omitted by S.I. 2020/1354 reg. 2(4)(f)
- Art. 4(8) substituted by S.I. 2020/1354 reg. 2(4)(g)
- Art. 5 substituted by S.I. 2020/1354 reg. 2(5)
- Art. 6 omitted by S.I. 2020/1354 reg. 2(6)
- Art. 7 substituted by S.I. 2020/1354 reg. 2(7)
- Art. 8 substituted by S.I. 2020/1354 reg. 2(8)
- Art. 9(1) words substituted by S.I. 2020/1354 reg. 2(9)(a)(i)
- Art. 9(1) words substituted by S.I. 2020/1354 reg. 2(9)(a)(ii)
- Art. 9(3) words omitted by S.I. 2020/1354 reg. 2(9)(b)(i)
- Art. 9(3) words substituted by S.I. 2020/1354 reg. 2(9)(b)(ii)
- Art. 10(1) words inserted by S.I. 2020/1354 reg. 2(10)(a)
- Art. 10(3) omitted by S.I. 2020/1354 reg. 2(10)(b)
- Art. 11 substituted by S.I. 2020/1354 reg. 2(11)
- Art. 12 omitted by S.I. 2020/1354 reg. 2(12)
- Art. 13(1) substituted by S.I. 2020/1354 reg. 2(13)
- Art. 14 words omitted by S.I. 2020/1354 reg. 2(14)

Changes and effects yet to be applied to the whole legislation item and associated provisions

- Signature words omitted by S.I. 2020/1354 reg. 2(15)(a)
- Art. 1(2)(a) words substituted by S.I. 2020/1354 reg. 2(2)(a)
- Art. 1(2)(d) inserted by S.I. 2020/1354 reg. 2(2)(b)
- Art. 2(2)(a) words substituted by S.I. 2020/1354 reg. 2(3)(b)(i)
- Art. 2(2)(b) words substituted by S.I. 2020/1354 reg. 2(3)(b)(i)
- Art. 2(2)(b) words substituted by S.I. 2020/1354 reg. 2(3)(b)(ii)
- Art. 2(3) inserted by S.I. 2020/1354 reg. 2(3)(c)
- Art. 4(2)(d) substituted by S.I. 2020/1354 reg. 2(4)(b)(ii)
- Art. 4(2)(e) words substituted by S.I. 2020/1354 reg. 2(4)(b)(iii)
- Art. 4(3A) inserted by S.I. 2020/1354 reg. 2(4)(d)
- Art. 16 inserted by S.I. 2020/1354 reg. 2(15)(b)