

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)

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Strasbourg, 11 May 2016.

For the European Parliament

The President

M. SCHULZ

For the Council

The President

J.A. HENNIS-PLASSCHAERT

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.

[View outstanding changes](#)

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\(15\)\(b\)](#)