
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Commission to adopt delegated acts to amend Annex I (List of tiered-priced products) of Regulation (EU) 2016/793 has been replaced by a power for the Secretary of State to add products to Annex I and a power for the Secretary of State to remove products from Annex I by regulations (see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Annex III (Percentages referred to in Article 3) and Annex IV (Scope of diseases) of Regulation (EU) 2016/793 has been replaced by a power for the Secretary of State to amend these Annexes by regulations.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for the Commission to draw up a report after 5 years in respect of the delegation of power to the Commission has been replaced by a requirement for the Secretary of State to carry out a review of Regulation (EU) 2016/793 and publish a report which, in particular, sets out the use of the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.