



Medicines and Medical Devices Act 2021

2021 CHAPTER 3

PART 3

VETERINARY MEDICINES

CHAPTER 1

REGULATIONS

10 Power to make regulations about veterinary medicines

- (1) The appropriate authority may by regulations make provision specified in sections 11 and 12 amending or supplementing the Veterinary Medicines Regulations 2013 (S.I. 2013/2033).
- (2) In making regulations under subsection (1), the appropriate authority's overarching objective must be to promote one or more of the following—
 - (a) the health and welfare of animals;
 - (b) the health and safety of the public;
 - (c) the protection of the environment.
- (3) In considering whether regulations under subsection (1) would contribute to this objective, the appropriate authority must have regard to—
 - (a) the safety of veterinary medicines;
 - (b) the availability of veterinary medicines;
 - (c) the likelihood of the relevant part of the United Kingdom being seen as a favourable place in which to—
 - (i) develop veterinary medicines, or
 - (ii) manufacture or supply veterinary medicines.
- (4) Where regulations under subsection (1) may have an impact on the safety of veterinary medicines, the appropriate authority may make the regulations only if the authority considers that the benefits of doing so outweigh the risks.

Changes to legislation: There are currently no known outstanding effects for the Medicines and Medical Devices Act 2021, CHAPTER 1. (See end of Document for details)

- (5) In subsection (3)(c), “relevant part of the United Kingdom” means—
- (a) so far as the regulations relate to England and Wales and Scotland, those parts of the United Kingdom, and
 - (b) so far as the regulations relate to Northern Ireland, that part of the United Kingdom.
- (6) In this Part, “appropriate authority” means—
- (a) in relation to England and Wales and Scotland, the Secretary of State, and
 - (b) in relation to Northern Ireland—
 - (i) the Department of Agriculture, Environment and Rural Affairs in Northern Ireland, or
 - (ii) the Department of Agriculture, Environment and Rural Affairs in Northern Ireland and the Secretary of State acting jointly.

11 Manufacture, marketing, supply and field trials

- (1) Regulations under section 10(1) may make provision about—
- (a) authorisations to manufacture veterinary medicines,
 - (b) authorisations to import veterinary medicines,
 - (c) authorisations to distribute veterinary medicines by way of wholesale dealing,
 - (d) marketing authorisations,
 - (e) marketing, importing or distributing active substances,
 - (f) the categories of person who may supply veterinary medicines,
 - (g) requirements that must be met in relation to the supply of veterinary medicines,
 - (h) the registration of persons who supply or offer to supply veterinary medicines by means of the internet,
 - (i) the circumstances in which veterinary medicines may be administered,
 - (j) notification and reporting requirements in relation to veterinary medicines (or things purporting to be veterinary medicines) that have been placed on the market,
 - (k) the labelling and packaging of veterinary medicines or the information that must be supplied with them or made available in relation to them,
 - (l) advertising with regard to veterinary medicines, or
 - (m) animal test certificates granted under the Veterinary Medicines Regulations 2013 (S.I. 2013/2033) for research purposes.
- (2) Regulations under section 10(1) may make provision corresponding or similar to provision in the following EU Regulations—
- (a) Regulation (EU) 2019/4 of the European Parliament and of the Council of 11 December 2018 on the manufacture, placing on the market and use of medicated feed, amending Regulation (EC) No 183/2005 of the European Parliament and of the Council and repealing Council Directive 90/167/EEC;
 - (b) Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC.

12 Fees, offences, powers of inspectors, costs

- (1) Regulations under section 10(1) may make provision—
 - (a) about the charging of fees in connection with the exercise of a function conferred by a veterinary medicines provision,
 - (b) creating a criminal offence of failing to comply with a provision made in the regulations,
 - (c) applying powers of entry or other powers of an inspector in the Veterinary Medicines Regulations 2013 (S.I. 2013/2033) with or without modification in relation to a prohibition or requirement in provision made in regulations under section 10(1), or
 - (d) about the recovery of costs incurred in the administration of improvement notices or seizure notices under the Veterinary Medicines Regulations 2013 (see regulations 38 and 41).
- (2) Regulations under section 10(1) may not provide for an offence to be punishable with a sentence of imprisonment of more than two years.
- (3) Regulations applying powers of entry in reliance on subsection (1)(c) may not confer a power of entry in respect of premises used wholly or mainly as a private dwelling unless those premises, or any part of them, are approved, registered or authorised for the sale or supply of veterinary medicines under a veterinary medicines provision.
- (4) In this section, “veterinary medicines provision” means a provision in—
 - (a) regulations under section 10(1), or
 - (b) the Veterinary Medicines Regulations 2013.

Changes to legislation:

There are currently no known outstanding effects for the Medicines and Medical Devices Act 2021, CHAPTER 1.