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.

(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.

CHAPTER 2

INTERNATIONAL AGREEMENTS: DISCLOSURE OF INFORMATION

13 Disclosure of information in accordance with international agreements

(1) This section applies to information which a relevant authority holds in connection with veterinary medicines.

(2) The relevant authority may disclose information to a relevant person outside the United Kingdom where—

(a) the disclosure is required for the purpose of giving effect to an international agreement or arrangement concerning the regulation of veterinary medicines, and

(b) the relevant authority considers that the disclosure is in the public interest.

(3) The relevant authority may not disclose commercially sensitive information in reliance on subsection (2) unless the relevant authority—

(a) considers that it is necessary to do so for the purpose mentioned in that subsection, and

(b) is satisfied that the making of the disclosure is proportionate to what is sought to be achieved by it.

(4) Except as provided by subsection (5), the disclosure of information in accordance with this section does not breach—

(a) an obligation of confidence owed by the person making the disclosure, or

(b) any other restriction on the disclosure of the information (however imposed).

(5) Nothing in this section authorises a disclosure of information which—

(a) contravenes the data protection legislation (but in determining whether a disclosure would do so, take into account the powers conferred by this section), or

(b) is prohibited by any of Parts 1 to 7 or Chapter 1 of Part 9 of the Investigatory Powers Act 2016.

(6) This section does not limit the circumstances in which information may be disclosed under any other enactment or rule of law.

(7) In this section—

"commercially sensitive information" means commercial information whose disclosure the relevant authority thinks might significantly harm the legitimate business interests of the undertaking to which it relates;

"data protection legislation" has the meaning given by section 3(9) of the Data Protection Act 2018;

"relevant authority" means—

(a) the Secretary of State, or

(b) the Department of Agriculture, Environment and Rural Affairs in Northern Ireland;

"relevant person" means—

(a) the government of a country or territory outside the United Kingdom;

(b) a person who exercises functions on behalf of such a government;

(c) any other person who exercises functions or provides services relating to veterinary medicines in a country or territory outside the United Kingdom;

(d) an international organisation that exercises functions or provides services relating to veterinary medicines.

CHAPTER 3

INTERPRETATION ETC

14 Interpretation of Part 3 and supplementary provision

(1) In this Part—

"active substance" means any substance or mixture of substances intended to be used in the manufacture of a veterinary medicine that, when used in its production, becomes an active ingredient of that medicine;

"appropriate authority" has the meaning given by section 10(6);

"manufacture" includes assembly;

"marketing authorisation" means an authorisation to market a veterinary medicine in the United Kingdom;

"veterinary medicine" means a veterinary medicinal product within the meaning given by regulation 2 of the Veterinary Medicines Regulations 2013 (S.I. 2013/2033).

(2) In the Animals (Scientific Procedures) Act 1986, in section 2 (regulated procedures), in subsection (8)(d), after "the Veterinary Medicines Regulations 2011" insert " or the Veterinary Medicines Regulations 2013 ".

Changes to legislation:
There are currently no known outstanding effects for the Medicines and Medical Devices Act 2021, PART 3.