Medicines and Medical Devices Act 2021

2021 CHAPTER 3

PART 2

HUMAN MEDICINES

CHAPTER 1

REGULATIONS

2 Power to make regulations about human medicines

(1) The appropriate authority may by regulations make provision specified in sections 3 to 7 amending or supplementing the law relating to human medicines.

(2) In making regulations under subsection (1), the appropriate authority's overarching objective must be safeguarding public health.

(3) In considering whether regulations under subsection (1) would contribute to this objective, the appropriate authority must have regard to—

(a) the safety of human medicines;

(b) the availability of human medicines;

(c) the likelihood of the relevant part of the United Kingdom being seen as a favourable place in which to—

(i) carry out research relating to human medicines,

(ii) conduct clinical trials, or

(iii) manufacture or supply human medicines.

(4) Where regulations under subsection (1) may have an impact on the safety of human 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 Health in Northern Ireland, or

(ii) the Department of Health in Northern Ireland and the Secretary of State acting jointly.

3 Manufacture, marketing and supply

(1) Regulations under section 2(1) may make provision about—

(a) authorisations to manufacture human medicines,

(b) authorisations to import human medicines,

(c) authorisations to distribute human medicines by way of wholesale dealing,

(d) marketing authorisations,

(e) manufacturing, importing or distributing active substances,

(f) brokering in relation to human medicines,

(g) the registration of the premises of pharmacy businesses,

(h) the recording of information about the supply of human medicines,

(i) notification and reporting requirements in relation to human medicines that have been placed on the market,

(j) the labelling and packaging of human medicines or the information that must be supplied with them or made available in relation to them,

(k) advertising with regard to human medicines,

(l) the registration of persons who supply or offer to supply human medicines by means of the internet,

(m) the requirements that must be met in relation to a prescription,

(n) prohibitions in the provisions mentioned in subsection (2), or

(o) the use of tissues or cells (within the meanings given by regulation 5(1) of the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (S.I. 2007/1523)) in relation to human medicines.

(2) Subsection (1)(n) refers to the following provisions in the Human Medicines Regulations 2012 (S.I. 2012/1916)—

(a) regulation 214 and Schedule 13 (sale or supply of prescription only medicines),

(b) regulation 215 and Schedule 14 (prescribing and administration by supplementary prescribers),

(c) regulation 220 (sale or supply of human medicines not subject to general sale),

(d) regulation 221 and Schedule 15 (sale or supply of medicinal products subject to general sale), and

(e) regulation 249 and Schedule 22 (restrictions on persons to be supplied with medicinal products).

4 Falsified medicines

(1) Regulations under section 2(1) may make provision about—

(a) the prevention of the supply of falsified human medicines, or

(b) the use, retention and disclosure, for any purpose to do with human medicines, of information collected for the purpose of preventing the supply of falsified human medicines.

(2) Provision made in reliance on subsection (1)(a) may (among other things) make provision—

(a) for human medicines that are subjects of a marketing authorisation to be supplied in packs that—

(i) carry unique identifiers associated with the products, and

(ii) are protected with anti-tamper devices,

(b) for checks to be carried out in relation to packs that have or should have such a unique identifier,

(c) about the infrastructure, systems and processes required for the allocation and checking of unique identifiers, including provision about—

(i) who is to set up the infrastructure, systems and processes,

(ii) who is to maintain them, and

(iii) who is to pay for them.

(3) In making regulations in reliance on subsection (1), the appropriate authority must have regard to the importance of ensuring that information is retained securely.

5 Clinical trials

(1) Regulations under section 2(1) may make provision—

(a) corresponding or similar to provision in the EU Clinical Trials Regulation,

(b) about authorisations concerning clinical trials in the United Kingdom, including applications for an assessment of the ethics of a proposed clinical trial,

(c) about notification and reporting requirements in relation to clinical trials,

(d) about requirements that must be met before a clinical trial may be carried out, or

(e) relating to the conduct of clinical trials.

(2) In subsection (1)(a), "EU Clinical Trials Regulation" means Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC.

6 Fees, offences, powers of inspectors

(1) Regulations under section 2(1) may make provision—

(a) about the charging of fees in connection with the exercise of a function conferred by a human medicines provision,

(b) creating a criminal offence of failing to comply with a provision made in the regulations, or

(c) applying relevant powers of entry or other powers of inspectors with or without modification in relation to a prohibition or requirement in provision made in the regulations.

(2) Regulations under section 2(1) may not provide for an offence to be punishable with a sentence of imprisonment of more than two years.

(3) In subsection (1), "relevant powers of entry or other powers of inspectors" means powers of entry or powers of inspectors in—

(a) Part 8 of the Medicines Act 1968;

(b) the Medicines for Human Use (Clinical Trials) Regulations 2004 (S.I. 2004/1031);

(c) Part 16 of the Human Medicines Regulations 2012 (S.I. 2012/1916).

(4) In this Part, "human medicines provision" means a provision in—

(a) regulations under section 2(1),

(b) the Human Medicines Regulations 2012, or

(c) the Medicines for Human Use (Clinical Trials) Regulations 2004.

7 Emergencies

(1) Regulations under section 2(1) may make provision about the disapplication of a human medicines provision in circumstances which give rise to a need to protect the public from a risk of serious harm to health.

(2) Regulations made in reliance on subsection (1) may provide for the disapplication to be subject to—

(a) conditions set out in the regulations;

(b) conditions set out in a protocol published by the appropriate authority.

(3) Where regulations made in reliance on subsection (1) provide that the appropriate authority may publish a protocol setting out conditions, the regulations must provide—

(a) that the appropriate authority may withdraw or amend the protocol, and

(b) that the protocol is to have effect only for a period of time specified in the protocol.

CHAPTER 2

INTERNATIONAL AGREEMENTS: DISCLOSURE OF INFORMATION

8 Disclosure of information in accordance with international agreements

(1) This section applies to information which a relevant authority holds in connection with human 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 human 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 subsections (5) and (6), 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 patient information without the consent of the individual to whom that information relates.

(6) 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.

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

(8) 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;

"patient information" means information (however recorded) which—

(a) relates to—

(i) the physical or mental health or condition of an individual,

(ii) the diagnosis of an individual's condition, or

(iii) an individual's care or treatment,

or is (to any extent) derived directly or indirectly from information relating to any of those matters, and

(b) identifies the individual or enables the individual to be identified (whether by itself or in combination with other information);

"relevant authority" means—

(a) the Secretary of State, or

(b) the Department of Health 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 human medicines in a country or territory outside the United Kingdom;

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

CHAPTER 3

INTERPRETATION

9 Interpretation of Part 2

In this Part—

"active substance" has the meaning given by regulation 8 of the Human Medicines Regulations 2012 (S.I. 2012/1916);

"appropriate authority" has the meaning given by section 2(6);

"clinical trial" has the meaning given by regulation 2(1) of the Medicines for Human Use (Clinical Trials) Regulations 2004 (S.I. 2004/1031);

"EU Clinical Trials Regulation" has the meaning given by section 5(2);

"falsified human medicine" means a falsified medicinal product within the meaning given by regulation 8 of the Human Medicines Regulations 2012;

"human medicine" means a medicinal product within the meaning given by regulation 2 of the Human Medicines Regulations 2012;

"human medicines provision" has the meaning given by section 6(4);

"law relating to human medicines" means—

(a) sections 10 and 15, and Part 4, and section 131 of the Medicines Act 1968 (which make provision relating to pharmacies),

(b) the Human Medicines Regulations 2012,

(c) the Medicines for Human Use (Clinical Trials) Regulations 2004, and

(d) the Medicines (Products for Human Use) (Fees) Regulations 2016 (S.I. 2016/190);

"manufacture" includes assembly;

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

"pharmacy business" means a business (other than a professional practice carried on by a doctor or dentist) which consists of or includes the sale of medicinal products that are not subject to general sale;

"supplying" includes administering within the meaning given by regulation 8 of the Human Medicines Regulations 2012 (and related expressions are to be read accordingly).