Medicines and Medical Devices Act 2021

2021 CHAPTER 3

PART 2

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).

Changes to legislation:
There are currently no known outstanding effects for the Medicines and Medical Devices Act 2021, Section 9.