



# 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;

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**Changes to legislation:** There are currently no known outstanding effects for the Medicines and Medical Devices Act 2021, Section 9. (See end of Document for details)

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“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.