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STATUTORY INSTRUMENTS

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**2019 No. 1385**

**EXITING THE EUROPEAN UNION  
CONSUMER PROTECTION  
MEDICINES**

The Human Medicines and Medical Devices  
(Amendment etc.) (EU Exit) Regulations 2019

*Made - - - - 23rd October 2019*

*Coming into force in accordance with regulation 1*

**THE HUMAN MEDICINES AND MEDICAL DEVICES  
(AMENDMENT ETC.) (EU EXIT) REGULATIONS 2019**

1. Citation and commencement
  2. Amendment of the Human Medicines (Amendment etc.) (EU Exit) Regulations 2019
  3. Amendment of the Medical Devices (Amendment etc.) (EU Exit) Regulations 2019
- Signature

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SCHEDULE 1 — Amendment of the Human Medicines (Amendment etc.) (EU Exit) Regulations 2019

1. Interpretation
2. Amendment of regulation 15 (amendment of regulation 18 of the 2012 Regulations – wholesale dealing in medicinal products)
3. Amendment of regulation 17 (amendment of regulation 19 of the 2012 Regulations – exemptions from requirement for wholesale dealer's licence)
4. Amendment of regulation 47 (amendment of regulation 48 of the 2012 Regulations – application of Part 5)
5. Amendment of regulation 56 (substitution of regulation 51 of the 2012 Regulations - applications relating to generic medicinal products)
6. Amendment of regulation 58 (amendment of regulation 53 of the 2012 Regulations - applications relating to similar biological medicinal products)

**Changes to legislation:** *There are currently no known outstanding effects for the The Human Medicines and Medical Devices (Amendment etc.) (EU Exit) Regulations 2019. (See end of Document for details)*

7. Amendment of regulation 63 (amendment of Schedule 11 to the 2012 Regulations – advice and representations)
8. Amendment of regulation 139 (amendment of regulation 177 of the 2012 Regulations – application of Part 11 (pharmacovigilance) and interpretation)
9. Amendment of Schedule 6 (insertion of Schedule 12A into the 2012 Regulations)
10. Amendment of Schedule 7 (insertion of Schedule 33A into the 2012 Regulations)

SCHEDULE 2 — Amendment of the Medical Devices (Amendment etc.) (EU Exit) Regulations 2019

1. Interpretation
2. Amendment of regulation 3 (amendment of Part I of the 2002 Regulations)
3. Amendment of regulation 4 (amendment of Part II of the 2002 Regulations)
4. Amendment of regulation 5 (amendment of Part III of the 2002 Regulations)
5. Amendment of regulation 6 (amendment of Part IV of the 2002 Regulations)
6. Amendment of regulation 7 (amendment of Part V of the 2002 Regulations)
7. Amendment of regulation 8 (amendment of Part VI of the 2002 Regulations)
8. Amendment of regulation 9 (amendment of Part VII of the 2002 Regulations)
9. Amendment of regulation 10 (insertion of Part VIII into the 2002 Regulations)
10. Amendment of regulation 11 (insertion of new Part IX into the 2002 Regulations)
11. Amendment of regulation 12 (new Schedules to the 2002 Regulations)

Explanatory Note

**Changes to legislation:**

There are currently no known outstanding effects for the The Human Medicines and Medical Devices (Amendment etc.) (EU Exit) Regulations 2019.