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STATUTORY RULES OF NORTHERN IRELAND

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**2019 No. 10**

**MEDICINES**

**The Human Medicines (Amendment) Regulations 2019**

*Made* - - - - - *14th January 2019*

*Laid before Parliament* *18th January 2019*

*Coming into force* *9th February 2019*

**THE HUMAN MEDICINES (AMENDMENT) REGULATIONS 2019**

1. Citation and commencement
2. Amendment of the Human Medicines Regulations 2012
3. Amendment of regulation 8 (general interpretation)
4. Amendment of regulation 36 (conditions for manufacturer's licence)
5. Amendment of Regulation 39 (further requirements for manufacturer's licence)
6. Amendment of regulation 42 (conditions for wholesale dealer's licence)
7. Insertion of regulation 43A (requirement for wholesale dealers to decommission the unique identifier)
8. Insertion of regulation 94A (offences relating to Commission Regulation 2016/161)
9. Insertion of regulation 226A (sale etc by a pharmacist in accordance with a serious shortage protocol)
10. Insertion of regulations 255A to 255C
11. Insertion of regulation 257A and 257B
12. Amendment of regulation 268 (enforcement relating to packaging and package leaflets: holder of authorisation etc)
13. Amendment of regulation 269 (offences relating to packaging and package leaflets: other persons)
14. Amendment of regulation 323 (enforcement in England, Wales and Scotland)
15. Amendment of regulation 327 (powers of inspection, sampling and seizure)
16. Amendment of regulation 346 (Secretary of State to carry out a review of certain provisions)
17. Amendment of Schedule 7 (qualified persons)
18. Amendment of Schedule 17 (exemption for sale, supply or administration by certain persons)

**Status:** This is the original version (as it was originally made). This item of legislation is currently only available in its original format.

19. Amendment of Schedule 24 (packaging information requirements)  
Signature  
Explanatory Note