
STATUTORY INSTRUMENTS

2021 No. 1452

MEDICINES

The Human Medicines (Amendment) (Supply to Northern Ireland) Regulations 2021

Made - - - - 15th December 2021
Laid before Parliament 16th December 2021
Coming into force 1st January 2022

THE HUMAN MEDICINES (AMENDMENT) (SUPPLY TO NORTHERN IRELAND) REGULATIONS 2021

1. Citation, commencement and extent
2. Amendments to the Human Medicines Regulations 2012
3. Amendments to regulation 5 (classification of medicinal products)
4. Amendments to regulation 8 (general interpretation)
5. Amendments to regulation 18 (wholesale dealing in medicinal products)
6. Amendment to regulation 19 (exemptions from requirement for wholesale dealer's licence)
7. Amendments to regulation 26 (general power to suspend, revoke or vary licences)
8. Amendments to regulation 37 (manufacturing and assembly)
9. Amendment to regulation 39 (further requirements for manufacturer's licence)
10. Amendments to regulation 42 (conditions for wholesale dealer's licence)
11. New regulation 43ZA (obligations of licence holder – listed NIMAR products)
12. Amendment to regulation 45 (requirement as to responsible persons)
13. Amendment to regulation A81 (application of regulations 81 to 94)
14. New regulation 167A (NIMAR supply to Northern Ireland) and new regulation 167B (list of NIMAR products)
15. Amendment to regulation 187 (recording obligations on holders)
16. Amendment to regulation 188 (reporting obligations on holders)
17. Amendment to regulation 229 (exemption for supply by national health service bodies and local authorities)
18. Amendment to regulation 230 (exemption for supply etc under a PGD to assist doctors or dentists)

Status: This is the original version (as it was originally made).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 to regulation 231 (exemption for supply etc under a PGD by independent hospitals etc)
20. Amendment to regulation 233 (exemption for supply etc under a PGD by person conducting a retail pharmacy business)
21. Amendment to regulation 234 (exemption for supply etc of products under a PGD to assist the police etc)
22. Amendment to regulation 247A (protocols relating to coronavirus and influenza vaccinations and immunisations)
23. Amendment to regulation 346 (review)
24. Amendments to Schedule 4 (standard provisions of licences under Part 3) Part 2 (manufacturer's licence relating to the import of medicinal products from a state other than an EEA State/Country other than an Approved Country for Import)
25. In Schedule 4, after paragraph 23, insert— The licence holder in Great Britain must take all reasonable...
26. Amendment to Schedule 7 (qualified persons) Part 3 (obligations of qualified person)
Signature
Explanatory Note