STATUTORY INSTRUMENTS

2020 No. 1488

EXITING THE EUROPEAN UNION
MEDICINES

The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020

Made - - - - 8th December 2020

Coming into force in accordance with regulation 1

THE HUMAN MEDICINES (AMENDMENT ETC.) (EU EXIT) REGULATIONS 2020

PART 4 — Amendment of Part 5 (amendment of Part 5 (marketing authorisations))

35. In regulation 47 (amendment of regulation 48 (application of Part...
36. In regulation 48 (amendment of regulation 49 (application for grant...
37. In regulation 49 (amendment of regulation 50 (accompanying material))—
38. In regulation 50 (amendment of Schedule 8 (material to accompany...
39. After regulation 51 (amendment of Schedule 8A (material to accompany...
40. In regulation 53 (new regulation 50A to 50J (applications in...
41. For regulation 56 (substitution of regulation 51 (applications relating to...
42. For regulation 57 (amendment of regulation 52 (applications relating to...
43. For regulation 58 (amendment of regulation 53 (applications relating to...
44. For regulation 60 (amendment of regulation 55 (applications relating to...
45. In regulation 62 (amendment of regulation 58 (consideration of application))—...
46. In regulation 63 (amendment of Schedule 11 (advice and representations)) —...
47. In regulation 64 (insertion of provisions concerning consideration of certain...
48. In regulation 65 (amendment of regulation 59 (conditions of UK...
49. For regulation 66 (amendment of regulation 60 (conditions of UK...
50. In regulation 67 (insertion of new regulations 60A (condition as...
51. In regulation 68 (amendment of regulation 61 (conditions of UK...
52. For regulation 69 (amendment of regulation 64 (duties of licensing...
53. In regulation 70 (obligation of licensing authority in case of...
54. In regulation 72 (validity of conditional marketing authorisation and variation...
55. In regulation 74 (amendment of regulation 66 (application for renewal...
56. After regulation 76 (renewal of conditional marketing authorisation) insert — Amendment...
57. In regulation 77 (amendment of regulation 68 (revocation, variation and...
58. In regulation 80(2) (amendment of regulation 71 (withdrawal of medicinal...
59. For regulation 81 (amendment of regulation 72 (sale etc of...
60. In regulation 82 (amendment of regulation 73 (obligation to notify...
61. For regulation 84 (amendment of regulation 76 (obligation in relation...
62. Omit regulation 85 (amendment of regulation 77 (record-keeping obligations)).
63. Omit regulation 86 (amendment of regulation 78 (obligation to ensure...
64. In regulation 87 (post authorisation requirements in relation to UK...
65. For regulation 88 (omission of regulation 79 (failure to provide...
66. In regulation 89 (amendment of regulation 80 (urgent safety restrictions)) —...
67. For regulation 90 (omission of regulations 81 to 94 (offences...
68. For regulation 91 (omission of regulation 94A (offences relating to...
69. For regulation 92 (amendment of regulation 95 (offences in connection...
70. Omit regulation 93 (amendment of regulation 96 (provision of misleading...
71. In regulation 94 (amendment of regulation 97 (breach of pharmacovigilance...
72. Omit regulation 95 (amendment of regulation 98 (general offence of...
73. Omit regulation 96 (amendment of regulation 99 (penalties)).
74. Omit regulation 97 (amendment of regulation 101 (defences)).
75. In regulation 98 (amendment of regulation 102 (regulation-making power to...