

## SCHEDULES

### SCHEDULE 2

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

### PART 17

Amendment of Part 18 (amendment of Part 17 (miscellaneous and general))

**183.** Before regulation 224 (amendment of regulation 341 (decisions under the Human Medicines Regulations 2012)) insert—

**“Amendment of regulation 335 (contravention due to fault of another person)**

**224ZA.** In regulation 335(6)(b) for “268 and 269” substitute “268, 268A, 269 and 269A”.

**Amendment of regulation 336 (warranty as defence)**

**224ZB.** In regulation 336(3)(b) for “268 and 269” substitute “268, 268A, 269 and 269A”.

**Amendment of regulation 340 (presumptions)**

**224ZC.** In regulation 340(5) for “268 (offences relating to packaging and package leaflets: authorisation holders), 269 (offences relating to packaging and package leaflets: other persons)” substitute “268 (offences relating to packaging and package leaflets in Great Britain: authorisation holders), 268A (offences relating to packaging and package leaflets in Northern Ireland: authorisation holders), 269 (offences relating to packaging and package leaflets in Great Britain: other persons), 269A (offences relating to packaging and package leaflets in Northern Ireland: other persons)”.

**Amendment of Schedule 32 (transitional provisions and savings)**

**224ZD.** In paragraph 3(10) of Schedule 32 for “268 (offences relating to packaging and package leaflets: authorisation holders), 269 (offences relating to packaging and package leaflets: other persons)” substitute “268 (offences relating to packaging and package leaflets in Great Britain: authorisation holders), 268A (offences relating to packaging and package leaflets in Northern Ireland: authorisation holders), 269 (offences relating to packaging and package leaflets in Great Britain: other persons), 269A (offences relating to packaging and package leaflets in Northern Ireland: other persons)”.

**184.** For regulation 224 (amendment of regulation 341 (decisions under the Human Medicines Regulations 2012)) substitute—

**“224.** In regulation 341(4)—

(a) in paragraph (a), insert “UK” before “marketing authorisation”;

(b) after paragraph (a), insert—

“(aa) a decision to grant or revoke an EU marketing authorisation;”.

**185.** In regulation 225 (insertion of regulation 344A (modifications to deal with serious shortages) and 344B (regulation making powers)), in the inserted regulation 344A(5) for “exit day” substitute “IP completion day”.

**186.** For regulation 226 (amendment of regulation 345 (immunity from civil liability)) substitute—

“**226.** In regulation 345(5), for “marketing authorisation” substitute “UK marketing authorisation, EU marketing authorisation”.”.

**187.** In regulation 227 (amendment of regulation 346 (Secretary of State to carry out a review of certain provisions))—

(a) in paragraph (a), for “paragraphs (ia)” to “(xxviii)” substitute “paragraph (xix)”;

(b) in paragraph (b), for “paragraphs (ia) and (ivab)” substitute “paragraph (ia)”.