

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) ”.”.

Commencement Information

II Sch. 2 para. 183 in force at 31.12.2020 immediately before IP completion day, see [reg. 1](#)

Changes to legislation: There are currently no known outstanding effects for the The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020, PART 17. (See end of Document for details)

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;”.”.

Commencement Information

I2 Sch. 2 para. 184 in force at 31.12.2020 immediately before IP completion day, see [reg. 1](#)

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 ”.

Commencement Information

I3 Sch. 2 para. 185 in force at 31.12.2020 immediately before IP completion day, see [reg. 1](#)

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 ”.”.

Commencement Information

I4 Sch. 2 para. 186 in force at 31.12.2020 immediately before IP completion day, see [reg. 1](#)

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) ”.

Commencement Information

I5 Sch. 2 para. 187 in force at 31.12.2020 immediately before IP completion day, see [reg. 1](#)

Changes to legislation:

There are currently no known outstanding effects for the The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020, PART 17.