

## SCHEDULES

### SCHEDULE 2

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

#### PART 4

Amendment of Part 5 (amendment of Part 5 (marketing authorisations))

**67.** For regulation 90 (omission of regulations 81 to 94 (offences relation to EU marketing authorisations) substitute—

**“Application of regulations 81 to 94 (offences relating to EU marketing authorisations)**

**90.** Before regulation 81 (obligation to update information supplied in connection with EU application), insert—

**“Application of regulations 81 to 94**

**A81.** Regulations 81 to 94 apply in relation to medicinal products for sale or supply in Northern Ireland.”.

**Amendment of regulation 89 (offences in connection with withdrawal of product from market)**

**90A.** In regulation 89(1)(b) (offences in connection with withdrawal of product from market) for “any of Articles 36, 37 and 38” substitute “ Article 37 or 38 ”.

**Omission of regulation 91 (failure to notify results of third country clinical trials)**

**90B.** Omit regulation 91.”.

#### Commencement Information

**II** Sch. 2 para. 67 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, Paragraph 67.