

SCHEDULES

SCHEDULE 2 **U.K.**

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

PART 4 **U.K.**

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

78. In regulation 101 (amendment of regulation 108 (application for renewal of certificate)) for “for “European Union”” to the end substitute—

“for “must be established in the European Union” substitute—

“, where it is applying for renewal of—

(a) a COR(NI) and originally granted—

(i) in accordance with Chapter 4 of Title III of the 2001 Directive, must be established in the European Union;

(ii) on any other basis, must be established in the United Kingdom;

(b) a COR(GB) and originally granted—

(i) under the unfettered access route, must be established in Northern Ireland;

(ii) other than under the unfettered access route, must be established in the United Kingdom;

(c) in the whole United Kingdom, must be established in the United Kingdom.””.

Commencement Information

II Sch. 2 para. 78 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 78.