

## 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))

**44.** For regulation 60 (amendment of regulation 55 (applications relating to new combinations of active substances)) substitute—

**“Substitution of regulation 55 (applications relating to new combinations of active substances)**

**60.** For regulation 55 substitute—

**“55.—**(1) This regulation applies to an application for a UK marketing authorisation for a relevant medicinal product that contains active substances, provided those active substances—

(a) have not been used in that combination for therapeutic purposes; and

(b) where the application is for—

(i) a UKMA(NI), have been used in medicinal products that have been the subject of a marketing authorisation under these Regulations, the 2001 Directive or Regulation (EC) No 726/2004;

(ii) a UKMA(GB), have been used in medicinal products that have been the subject of a marketing authorisation under these Regulations; or

(iii) a UKMA(UK), have been used in medicinal products that have been the subject of—

(aa) a UKMA(UK) under these Regulations; or

(bb) a relevant Northern Ireland authorisation.

(2) The applicant must provide the results of new pre-clinical tests or new clinical trials relating to that combination in accordance with paragraph 10 of Schedule 8, but does not need to provide scientific references relating to each individual active substance.

(3) In paragraph (1), “relevant Northern Ireland authorisation” means—

(a) a UKMA(NI) under these Regulations;

(b) a marketing authorisation under the 2001 Directive; or

(c) an EU marketing authorisation,

which authorises the sale or supply of a medicinal product in Northern Ireland.””.

**Changes to legislation:** There are currently no known outstanding effects for the The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020, Paragraph 44. (See end of Document for details)

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**Commencement Information**

**II** Sch. 2 para. 44 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 44.