

## SCHEDULES

### SCHEDULE 2

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

### PART 2

Amendment of Part 3 (amendment of Part 3 (manufacture and distribution of medicinal products and active substances))

12. In regulation 18 (amendment of Schedule 3 (applications for licences under Part 3))—

(a) for paragraph (2) substitute—

“(2) For paragraph 1(2)(g) substitute—

“(g) the name, address, qualifications and experience of the person with responsibility for quality control in relation to the medicinal products to be manufactured or assembled under the licence (and, if that responsibility is to be carried out by the holder of—

(i) in the case of a product for sale or supply in Great Britain, the UK marketing authorisation, certificate of registration or traditional herbal registration relating to the products, or

(ii) in the case of a product for sale or supply in Northern Ireland, the marketing authorisation, Article 126a authorisation, certificate of registration or traditional herbal registration relating to the products,

a statement of that fact);”;

(b) for paragraph (3) substitute—

“(3) For paragraph 2(1) substitute—

“2.—(1) This paragraph applies to an application for a manufacturer’s licence relating to the import from—

(a) in the case of an import into Great Britain, a country other than Northern Ireland or a country other than an approved country for import, or

(b) in the case of an import into Northern Ireland, a country other than an EEA State,

of medicinal products.”;

(c) in paragraph (4)(b)—

(i) for sub-paragraph (i) substitute—

“(i) for paragraph (i) substitute—

“(i) in the case of a product for sale or supply in Great Britain, a UK marketing authorisation,

(ia) in the case of a product for sale or supply in Northern Ireland, a marketing authorisation,”;

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Statutory Instrument: *The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 No. 1488*

- (ii) for sub-paragraph (ii) substitute—
  - “(ii) in paragraph (iv) before “an Article” insert “in the case of a product for sale or supply in Northern Ireland,” and”;
- (d) in paragraph (4)(c)(iii), in the inserted paragraph (iii), after “export” insert “from Great Britain”.