# SCHEDULES

## SCHEDULE 1

### Amendment of the Medicines for Human Use (Clinical Trials) (Amendment) (EU Exit) Regulations 2019

**4.** For regulation 18 (amendment of regulation 43 (qualified persons)) substitute—

"**18.** In regulation 43—

(a) for paragraphs (1) and (2) substitute—

"(1) Subject to paragraphs (4) and (5), the holder of a manufacturing authorisation must have at his disposal the services of at least one qualified person—

(a) where the manufacturing authorisation relates wholly to the import of an investigational medicinal product into Great Britain from an approved country for import, who must operate and be ordinarily resident in either the United Kingdom or an approved country for import, or

(b) in any other case, who must operate and be ordinarily resident in the United Kingdom, and

who is responsible for carrying out the duties referred to in paragraph 2.

(2) Subject to paragraphs (2A) and (2C), the qualified person is responsible for ensuring that—

(a) in the case of an investigational medicinal product manufactured in Northern Ireland, each production batch has been manufactured and checked in compliance with—

(i) the requirements of these Regulations;

(ii) the principles and guidelines of good manufacturing practice;

(iii) the product specification, as defined in Part 1 of Schedule 7; and

(iv) the request, particulars and documents submitted to the licensing authority under regulation 17 in respect of the clinical trial in which the product is to be used;

(b) in the case of an investigational medicinal product manufactured in Great Britain, each production batch has been manufactured and checked in compliance with—

(i) the requirements of these Regulations;

(ii) the principles and guidelines of good manufacturing practice, as modified by Schedule 2A to the 2012 Regulations or any regulations made under the power in regulation B17(1) of those Regulations;

(iii) the product specification, as defined in Part 1 of Schedule 7; and

(iv) the request, particulars and documents submitted to the licensing authority under regulation 17 in respect of the clinical trial in which the product is to be used;

(c) in the case of an investigational medicinal product imported into Northern Ireland from a country other than an EEA State, each production batch has been manufactured and checked in compliance with—

(i) standards of good manufacturing practice at least equivalent to the principles and guidelines of good manufacturing practice;

(ii) the product specification, as defined in Part 1 of Schedule 7; and

(iii) the request, particulars and documents submitted to the licensing authority under regulation 17 in respect of the clinical trial in which the product is to be used;

(d) in the case of an investigational medicinal product imported into Great Britain other than from Northern Ireland, each production batch has been manufactured and checked in compliance with—

(i) standards of good manufacturing practice at least equivalent to the principles and guidelines of good manufacturing practice, as modified by Schedule 2A to the 2012 Regulations or any regulations made under the power in regulation B17(1) of those Regulations;

(ii) the product specification, as defined in Part 1 of Schedule 7; and

(iii) the request, particulars and documents submitted to the licensing authority under regulation 17 in respect of the clinical trial in which the product is to be used.

(2A) The qualified person is not responsible for carrying out the controls in paragraph (2) where—

(a) the product is imported into Great Britain from a country that is included on the list referred to in regulation 43A ("approved country for import"); and

(b) the qualified person ensures that there is appropriate evidence to confirm that each production batch has been certified as provided for in Article 13 of the Directive, or such equivalent certification procedure as applies in the approved country for import.

(2B) The licensing authority must publish guidance on the evidence that it considers to be appropriate for the purposes of paragraph (2A)(b).

(2C) The qualified person is not responsible for carrying out the controls in paragraph (2) where—

(a) an investigational medicinal product—

(i) which has a marketing authorization other than a UKMA(GB), is imported into Northern Ireland as a comparator product; or

(ii) which has a marketing authorization, or has been approved for marketing in another country, is imported into Great Britain as a comparator product; and

(b) documentation cannot be obtained certifying that each production batch has been manufactured and checked in accordance with standards of

good manufacturing practice at least equivalent to those laid down in Commission Directive 2003/94/EC.

(2D) Where paragraph (2) does not apply by virtue of paragraph (2C), the qualified person is responsible for ensuring that each production batch has undergone all relevant analyses, tests or checks necessary to confirm its quality in accordance with the request, particulars and documents submitted to the licensing authority under regulation 17.

(2E) The qualified person is responsible for ensuring, in relation to an investigational medicinal product, that documentary evidence is produced that each batch of the product satisfies the provisions of paragraph (2), (2A) or (2D) (as the case may be).

(2F) The documentary evidence referred to in paragraph (2E) must be—

(a) kept up to date as operations are carried out; and

(b) available for inspection by the licensing authority for a period of at least five years beginning with the date on which the documentary evidence is produced.";

(b) for paragraph (5) substitute—

"(5) For the purposes of this paragraph, but without prejudice to paragraph (6) below, the holder of the authorisation may regard a person as satisfying the provisions of the said Article 49 or 50, as respects formal qualifications if—

(a) in relation to the obligation in paragraph (1)(a), he is already named as a qualified person in respect of an authorisation issued in an approved country for import; or

(b) he produces evidence that—

(i) he is a member of—

(aa) the Institute of Biology,

(bb) the Pharmaceutical Society,

(cc) the Royal Society of Chemistry, or

(dd) such other body as may appear to the licensing authority to be an appropriate body for the purpose of this paragraph; and

(ii) he is regarded by the body of which he is a member as so satisfying those provisions.".".

**Commencement Information**

**I1** Sch. 1 para. 4 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 4.