
STATUTORY INSTRUMENTS

2019 No. 775

**The Human Medicines (Amendment
etc.) (EU Exit) Regulations 2019**

PART 3

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

New regulation B17 and C17 (good manufacturing practice and good distribution practice)

13. After regulation A17^{M1} insert—

“Chapter 1A

Good manufacturing practice and good distribution practice

Regulations on good manufacturing practice

B17.—(1) The [^{F1}Secretary of State] may by regulations [^{F2}in respect of Great Britain] set out principles and guidelines of good manufacturing practice in respect of medicinal products and investigational medicinal products.

(2) Regulations under paragraph (1) may in particular make provisions as to—

- (a) inspections;
- (b) compliance with good manufacturing practice and, where relevant, the UK marketing authorisation [^{F3}or EU marketing authorisation];
- (c) quality assurance systems;
- (d) personnel;
- (e) premises and equipment;
- (f) documentation;
- (g) production;
- (h) quality control;
- (i) the contracting out of work;
- (j) complaints and product recall;
- (k) self-inspection.

(3) Subject to any provision made in regulations under paragraph (1), the principles and guidelines set out in the Good Manufacturing Practice Directive have effect [^{F4}in Great Britain] on and after [^{F5}IP completion day] as they had effect immediately before [^{F5}IP completion day], but subject to the modifications specified in Schedule 2A.

(4) The [^{F6}Secretary of State] may by regulations [^{F7}in respect of Great Britain] amend or revoke Schedule 2A.

Guidelines on good manufacturing practice and good distribution practice

C17.—(1) The licensing authority may publish [^{F8}in relation to the manufacture or assembly of a medicinal product in, or import to, Great Britain]—

- (a) detailed guidelines of good manufacturing practice in respect of medicinal products, and investigational medicinal products, referred to in Article 46(f) of the 2001 Directive, including guidelines as to the formalised risk assessment for ascertaining the appropriate good manufacturing practice for excipients;
- (b) principles and guidelines of good manufacturing practice for active substances, referred to in the first paragraph of point (f) of Article 46 and in Article 46b of that Directive;
- (c) principles and guidelines of good distribution practice referred to in the first paragraph of point (f) of Article 46, and Article 84, of that Directive.

(2) Guidelines or principles under paragraph (1) may replace, amend or otherwise modify any guidelines or principles published or adopted by the European Commission under the second, third, fourth or fifth paragraph of Article 47, or Article 84, of the 2001 Directive.

(3) Unless replaced by principles or guidelines published under paragraph (1), principles and guidelines published or adopted by the European Commission under the second, third, fourth or fifth paragraph of Article 47, or Article 84, of the 2001 Directive, as they applied immediately before [^{F9}IP completion day]^{M2}, continue to apply on and after [^{F9}IP completion day] (subject to any amendments or modifications published under paragraph (1)).

(4) Before exercising the power under paragraph (1), the licensing authority must consult such persons as it considers appropriate.

(5) The licensing authority may only exercise its power under paragraph (1) if it considers that it is necessary in order to take account of technical or scientific progress.

(6) If the licensing authority publishes principles and guidelines under paragraph (1), any reference in these Regulations to any principle or guideline adopted under the provisions of the 2001 Directive specified in those paragraphs is instead to be read as a reference to the principle or guideline published under paragraph (1), or that principle or guideline as amended or modified (as the case may be).”.

Textual Amendments

- F1** Words in reg. 13 substituted (31.12.2020 immediately before IP completion day) by [The Human Medicines \(Amendment etc.\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1488\), reg. 1, Sch. 2 para. 8\(a\)\(i\)\(aa\)](#)
- F2** Words in reg. 13 inserted (31.12.2020 immediately before IP completion day) by [The Human Medicines \(Amendment etc.\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1488\), reg. 1, Sch. 2 para. 8\(a\)\(i\)\(bb\)](#)
- F3** Words in reg. 13 inserted (31.12.2020 immediately before IP completion day) by [The Human Medicines \(Amendment etc.\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1488\), reg. 1, Sch. 2 para. 8\(a\)\(ii\)](#)
- F4** Words in reg. 13 inserted (31.12.2020 immediately before IP completion day) by [The Human Medicines \(Amendment etc.\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1488\), reg. 1, Sch. 2 para. 8\(a\)\(iii\)\(aa\)](#)

- F5** Words in reg. 13 substituted (31.12.2020 immediately before IP completion day) by [The Human Medicines \(Amendment etc.\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1488\)](#), reg. 1, **Sch. 2 para. 8(a)(iii)(bb)**
- F6** Words in reg. 13 substituted (31.12.2020 immediately before IP completion day) by [The Human Medicines \(Amendment etc.\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1488\)](#), reg. 1, **Sch. 2 para. 8(a)(iv)(aa)**
- F7** Words in reg. 13 inserted (31.12.2020 immediately before IP completion day) by [The Human Medicines \(Amendment etc.\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1488\)](#), reg. 1, **Sch. 2 para. 8(a)(iv)(bb)**
- F8** Words in reg. 13 inserted (31.12.2020 immediately before IP completion day) by [The Human Medicines \(Amendment etc.\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1488\)](#), reg. 1, **Sch. 2 para. 8(b)(i)**
- F9** Words in reg. 13 substituted (31.12.2020 immediately before IP completion day) by [The Human Medicines \(Amendment etc.\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1488\)](#), reg. 1, **Sch. 2 para. 8(b)(ii)**

Commencement Information

- I1** Reg. 13 in force at 31.12.2020 on IP completion day (in accordance with [2020 c. 1](#), **Sch. 5 para. 1(1)**), see reg. 1

Marginal Citations

- M1** Regulation A17 was inserted by [S.I. 2013/1855](#).
- M2** The principles and guidelines are available at: <https://www.gov.uk/guidance/eu-guidance-documents-referred-to-in-the-human-medicines-regulations-2012> and a hard copy may be obtained from the Medicines and Healthcare products Regulatory Agency at the address given in the Explanatory Note.

Changes to legislation:

There are currently no known outstanding effects for the The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019, Section 13.