DRAFT STATUTORY INSTRUMENTS

2019 No.

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.—(1) After regulation A17(**1**) insert—

"Chapter 1A

Good manufacturing practice and good distribution practice

Regulations on good manufacturing practice

B17.—(1) The Ministers may by regulations 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;

(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 on and after exit day as they had effect immediately before exit day, but subject to the modifications specified in Schedule 2A.

(4) The Ministers may by regulations amend or revoke Schedule 2A.

(**1**) Regulation A17 was inserted by S.I. 2013/1855.

Guidelines on good manufacturing practice and good distribution practice

C17.—(1) The licensing authority may publish—

(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 exit day(**2**), continue to apply on and after exit 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).”.

(**2**) 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.