DRAFT STATUTORY INSTRUMENTS

2019 No.

The Medicines for Human Use (Clinical Trials) (Amendment) (EU Exit) Regulations 2019

Insertion of regulation 57 (functions in relation to good clinical practice)

23. After regulation 56, insert—

"**Functions in relation to good clinical practice**

57.—(1) Regulations may—

(a) amend the conditions and principles of good clinical practice to take account of technical and scientific progress;

(b) specify requirements for documentation relating to a clinical trial which constitute the master file on the trial at the time the file is archived;

(c) amend or revoke the requirements of regulation 31A relating to the content of the trial master file; and

(d) require guidance published under regulation 58 to be taken into account when interpreting any enactment or other requirement to which the guidance relates.

(2) Any power to make regulations under paragraph (1)—

(a) is exercisable—

(i) in respect of Northern Ireland only, by the Minister of Health in Northern Ireland by statutory rule for the purposes of the Statutory Rules (Northern Ireland) Order 1979(**1**);

(ii) in respect of any part of the United Kingdom, by the Secretary of State by statutory instrument;

(b) in respect of Northern Ireland may be exercised by—

(i) the Minister of Health acting alone; or

(ii) the Secretary of State acting with the agreement of the Minister of Health;

(c) includes power to make—

(i) different provision for different purposes or different areas;

(ii) consequential, supplementary, incidental, transitional, transitory or saving provisions, including consequential amendments to these Regulations.

(3) Regulations under paragraph (1) are—

(a) in the case of a statutory instrument made by the Secretary of State, subject to annulment in pursuance of a resolution of either House of Parliament;

(**1**) S.I. 1979/1573 (NI 12).

(b) in the case of statutory rules made by the Minister of Health in Northern Ireland, subject to negative resolution within the meaning of section 41(6) of the Interpretation Act (Northern Ireland) 1954(**2**).

Detailed guidance

58. The licensing authority may publish guidance on—

(a) the application format and documentation to be submitted in an application for an ethics committee opinion, in particular regarding the information that is given to subjects, and on the appropriate safeguards for the protection of personal data;

(b) the format and contents of a request for authorisation of a clinical trial, as well as the documentation to be submitted to support that request, on the quality and manufacture of the investigational medicinal product, any toxicological and pharmacological tests, the protocol and clinical information on the investigational medicinal product including the investigator's brochure;

(c) the presentation and content of any proposed substantial amendment to the clinical trial authorisation insofar as it relates to the protocol;

(d) the declaration of the end of the clinical trial;

(e) the collection, verification and presentation of adverse event or adverse reaction reports, together with decoding procedures for unexpected serious adverse reactions;

(f) the content of essential documents forming part of the trial master file;

(g) the elements to be taken into account when evaluating investigational medicinal products for the purpose of regulation 43(2).".

(**2**) 1954 c.33 (NI).