STATUTORY INSTRUMENTS

2019 No. 744

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

Amendment of Schedule 7 (standard provisions for manufacturing authorisations)

[F1 25. In Part 1 of Schedule 7—

(a) for "In this Schedule," substitute "In this Schedule—";

(b) the definition of "product specification" becomes part of a list of definitions;

(c) before the definition of "product specification" insert—

""Commission Directive 2003/94/EC", in relation to the holder of an authorisation means—

(a) in the case of a holder in Great Britain—

(i) Commission Directive 2003/94/EC laying down the principles and guidelines of good manufacturing practice for medicinal products for human use and for investigational medicinal products for human use, as modified by Schedule 2A to the 2012 Regulations, or

(ii) if Regulations have been made under the powers in regulation B17(1) of the 2012 Regulations, and have come into force, those Regulations;

(b) in the case of a holder in Northern Ireland, Commission Directive 2003/94/EC laying down the principles and guidelines of good manufacturing practice for medicinal products for human use and for investigational medicinal products for human use;";

(d) in the definition of "product specification", for paragraph (a) substitute—

"(a) in the case of an investigational medicinal product manufactured before a request for authorisation to conduct the clinical trial involving those products has been made—

(i) in the case of an investigational medicinal product manufactured or assembled in Great Britain, in accordance with regulation 17, or

(ii) in the case of an investigational medicinal product manufactured or assembled in Northern Ireland, in accordance with regulation 17 or any equivalent provisions in any EEA State,

the specification for that product provided by the person who is to act as the sponsor of the proposed clinical trial,".**]**

F1 Reg. 25 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. 1 para. 9**

Commencement Information

I1 Reg. 25 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Changes to legislation:
There are currently no known outstanding effects for the The Medicines for Human Use (Clinical Trials) (Amendment) (EU Exit) Regulations 2019, Section 25.