DRAFT STATUTORY INSTRUMENTS

2019 No.

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

Amendment of regulation 2 (interpretation)

3.—(1) Regulation 2(1)(**1**) is amended as follows.

(2) For the definition of "Commission Directive 2003/94/EC" substitute—

""Commission Directive 2003/94/EC" means—

(a) 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(**2**), or

(b) if Regulations have been made under the powers in regulation B17(1) of the 2012 Regulations(**3**), and have come into force, those Regulations;".

(3) After the definition of "container" insert—

""country" means a country or territory;".

(4) In the definition of "export", for "a third country from an EEA State" substitute "another country from the United Kingdom".

(5) Omit the definition of "the GCP Directive".

(6) For the definition of "import" substitute—

""import" means import into the United Kingdom, whether by land, sea or air;".

(7) In the definition of "investigational medicinal product", before "marketing authorization" insert "UK".

(8) For the definition of "marketing authorization", substitute—

""marketing authorization" means—

(a) a UK marketing authorization, or

(b) an authorization granted by a regulatory body responsible for licensing medicinal products in a country that is included in the list referred to in regulation 2A(1);".

(9) In the definition of "non-interventional trial", before "marketing authorization", insert "UK".

(10) Omit the definition of "third country".

(11) After the definition of "trial site" insert—

""UK marketing authorization" means—

(a) a marketing authorisation granted by the licensing authority under the 2012 Regulations, or

(**1**) Regulation 2(1) was amended by S.I. 2004/3224, 2005/2759, 2006/562 and 1928, 2007/3101, 2008/941, 2011/2581, 2012/1479, 1641 and 1916, 2013/235 and 2016/696 and S.R. 2008/192.
(**2**) Schedule 2A is inserted by the Human Medicines (Amendment etc.) (EU Exit) Regulations 2019.
(**3**) Regulation B17 is inserted by the Human Medicines (Amendment etc.) (EU Exit) Regulations 2019.

(b) a product licence granted by the licensing authority for the purposes of section 7 of the Medicines Act 1968;".

(12) In the definition of "unexpected adverse reaction", in paragraph (a), after "summary of product characteristics" insert ", or equivalent document,".