STATUTORY INSTRUMENTS

2019 No. 744

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

Amendment of regulation 2 (interpretation)

3.—(1) Regulation 2(1) [M1] is amended as follows.

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

[[F1]""Commission Directive 2003/94/EC", other than in Parts 2 and 3 of Schedule 7, means—

(a) in the case of an investigational medicinal product manufactured or assembled in, or imported into, 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 an investigational medicinal product manufactured or assembled in, or imported into, 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; "**]**.

(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—

[[F2]""import", except in regulation 13 and Schedule 13, means import, or attempt to import—

(a) into Great Britain other than from Northern Ireland, or

(b) into Northern Ireland from a country other than an EEA State,

whether by land, sea or air and "imported" is to be construed accordingly;;"**]**.

[F3](7) . . . . . .

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

[[F4]""marketing authorization" means—

(a) a UK marketing authorization,

(b) an EU marketing authorisation (as defined in the 2012 Regulations), or

(c) 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);"**]**.

F5(9) . . . . . .

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

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

[F6""UK marketing authorization"—

(a) has the same meaning as "UK marketing authorisation" in the 2012 Regulations (and references to "UKMA(UK)", "UKMA(GB)" and "UKMA(NI)" in these Regulations should be construed in accordance with that definition); and

(b) includes 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, ".

F1 Words in reg. 3(2) 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. 1(a)**

F2 Words in reg. 3(6) 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. 1(b)**

F3 Reg. 3(7) omitted (31.12.2020 immediately before IP completion day) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 1 para. 1(c)**

F4 Words in reg. 3(8) 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. 1(d)**

F5 Reg. 3(9) omitted (31.12.2020 immediately before IP completion day) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 1 para. 1(e)**

F6 Words in reg. 3(11) 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. 1(f)**

Commencement Information

I1 Reg. 3 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 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.

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 3.