SCHEDULES

SCHEDULE 1

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

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1. In regulation 3 (amendment of regulation 2 (interpretation))—

(a) in paragraph (2), for the substituted definition of " Commission Directive 2003/94/EC " substitute—

""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;";

(b) in paragraph (6), for the substituted definition of " import " substitute—

""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;;";

(c) omit paragraph (7);

(d) in paragraph (8), for the substituted definition of " marketing authorization " substitute—

""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);";

(e) omit paragraph (9);

(f) in paragraph (11), for the inserted definition of "UK marketing authorization" substitute—

""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;".

Commencement Information

I1 Sch. 1 para. 1 in force at 31.12.2020 immediately before IP completion day, see **reg. 1**

Changes to legislation:
There are currently no known outstanding effects for the The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020, Paragraph 1.