SCHEDULES

SCHEDULE 1

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

2. In regulation 7 (amendment of regulation 13 (supply of investigational medicinal products for the purpose of clinical trials))—

(a) in paragraph (2), for the inserted sub-paragraph (b), substitute—

"(b) in the case of—

(i) an investigational medicinal product manufactured or assembled in the United Kingdom, the product has been manufactured or assembled—

(aa) in accordance with the terms of a manufacturing authorisation, or

(bb) in the case of assembly only, under the exemption in regulation 37;

(ii) an investigational medicinal product imported into Northern Ireland from an EEA State—

(aa) the product has been manufactured, assembled or imported into an EEA State in accordance with the terms of an authorisation referred to in Article 13 of the Directive granted by a competent authority of an EEA State, and

(bb) the production batch of investigational medicinal products of which the product is a part has been checked and certified by a qualified person pursuant to Article 13(3) and (4) of the Directive;

(iii) an investigational medicinal product imported into Northern Ireland from a country other than an EEA State, the product has been imported into Northern Ireland in accordance with the terms of a manufacturing authorisation;

(iv) an investigational medicinal product imported into Great Britain other than from Northern Ireland, the product has been imported in accordance with the terms of a manufacturing authorisation.";

(b) in paragraph (3), in the inserted paragraph (2A)—

(i) omit "UK";

(ii) after "marketing authorization" insert " or marketing authorisation issued by the competent authority of an EEA State in accordance with Directive 2001/83/EC ";

(c) for paragraph (5) substitute—

"(5) For paragraph (4) substitute—

"(4) The restriction in paragraph (1) shall not apply to—

(a) the sale or supply of a medicinal product in Great Britain in accordance with the terms of a UKMA(GB) or UKMA(UK), and

(b) the sale or supply of a medicinal product in Northern Ireland in accordance with—

(i) the terms of a UKMA(NI) or UKMA(UK), or

(ii) an EU marketing authorisation (as defined in the 2012 Regulations).”.”.

Commencement Information

I1 Sch. 1 para. 2 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 2.