SCHEDULES

SCHEDULE 4

Exemptions

PART 5

Healthcare

35.—(1) Any of the following—

(a) a person ("P") who—

(i) before travelling to the United Kingdom has made arrangements with a provider in the United Kingdom to receive healthcare (or, where P is a child, on whose behalf such arrangements have been made),

(ii) is in possession of written confirmation of the arrangements from the provider,

(iii) has travelled to the United Kingdom to receive that healthcare, and

(iv) is attending a place to receive that healthcare.

(b) a person who—

(i) is accompanying P for the purpose of providing necessary care or support to P in the circumstances referred to in sub-paragraph (1)(a)(iv), or

(ii) is travelling, for the purpose of so accompanying P, directly between the place where they are staying in accordance with regulation 26(2) and either of the places referred to in sub-paragraph (1)(a)(iv), where that person has travelled to the United Kingdom for that purpose and is in possession of the confirmation referred to in sub-paragraph (1)(a)(ii) or a copy of it,

(c) a child who is accompanying P or, where P is a child, any child who is accompanying a person referred to in sub-paragraph (1)(b),

(d) a live donor.

(2) For the purposes of this paragraph—

"healthcare" means all forms of healthcare provided for individuals, whether relating to mental or physical health, including healthcare in connection with giving birth,

"live donor" means a person who—

(a) has travelled to the United Kingdom for the purpose of donation of material which consists of or includes their human cells pursuant to arrangements made with a provider in the United Kingdom before travelling to the United Kingdom and which are to be used by the provider for the purpose of providing healthcare, and

(b) is in possession of written confirmation of the arrangements from the provider, and

"provider" means a provider of healthcare.

36.—(1) A person who has travelled to the United Kingdom for the purpose of transporting material which consists of, or includes, human cells or blood and which is to be used for the provision of healthcare by a healthcare provider.

(2) For the purposes of sub-paragraph (1)—

"blood" includes blood components, and

"healthcare" has the meaning given in paragraph 35.

37. A person who is an "inspector" within the meaning given in regulation 8(1) of the Human Medicines Regulations 2012(**1**) who has travelled to the United Kingdom to undertake activities in relation to their role as such a person.

38.—(1) A person who—

(a) has travelled to the United Kingdom to—

(i) conduct a clinical trial within the meaning of "conducting a clinical trial" in regulation 2(1) of the Medicines for Human Use (Clinical Trials) Regulations 2004(**2**),

(ii) undertake such activities as are necessary or expedient to prepare for the conduct of a clinical trial, or

(iii) carry out any necessary compliance activity in relation to a clinical trial that cannot be conducted remotely,

(b) is a "qualified person" within the meaning of regulation 43 of those Regulations, where they have travelled to the United Kingdom in order to undertake activities in relation to their role as such a person, or

(c) is a "sponsor" within the meaning given in regulation 2(1) of those Regulations, or carries out the functions or duties of a sponsor, of a clinical trial and has travelled to the United Kingdom to undertake activities in relation to a clinical trial.

(2) For the purposes of sub-paragraph (1), "clinical trial" has the meaning given in regulation 2(1) of the Medicines for Human Use (Clinical Trials) Regulations 2004.

39. A person who has travelled to the United Kingdom to—

(a) conduct a clinical investigation within the meaning of the Medical Devices Regulations 2002(**3**),

(b) undertake such activities as are necessary or expedient to prepare for the conduct of a clinical investigation, or

(c) carry out any other necessary compliance activity in relation to a clinical investigation that cannot be conducted remotely.

40. A person who is—

(a) a "qualified person" within the meaning of regulation 41(2) of the Human Medicines Regulations 2012,

(b) a "responsible person" within the meaning of regulation 45(1) of those Regulations,

where they have travelled to the United Kingdom in order to undertake activities in relation to their role as such a person.

(**1**) S.I. 2012/1916.
(**2**) S.I. 2004/1031.
(**3**) S.I. 2002/618.