SCHEDULE 2 Regulation 11

Insertion of new Schedule 8B (modifications of Annex I to the 2001 Directive)

1. After Schedule 8A to the Human Medicines Regulations 2012, insert—

"SCHEDULE 8B Regulation 8(1)

Modifications of Annex I to the 2001 Directive

Provision of Annex I	*Modification subject to which that provision is to be read*
Paragraph (1) of the Introduction and general principles	The reference to "Articles 8 and 10(1)" is to be read as a reference to regulation 50 of the Human Medicines Regulations 2012.
Paragraphs (1) and (2) of the Introduction and general principles	If the licensing authority has published guidelines under regulation 50(5B)(a) of the Human Medicines Regulations 2012, the reference to "the rules governing medicinal products in the European Community, Volume 2B, Notice to applicants, medicinal products for human use, presentation and content of the dossier, Common Technical Document" is to be read as a reference to that guidance.
Paragraph (4) of the Introduction and general principles	If the licensing authority has published guidelines under regulation 50(5B)(b) of the Human Medicines Regulations 2012, the reference to "the scientific guidelines relating to the quality, safety and efficacy of medicinal products for human use as adopted by the Committee for Proprietary Medicinal Products (CPMP) and the European Medicines Evaluation Agency (EMEA) and the other pharmaceutical Community guidelines published by the Commission in the different volumes of the rules governing medicinal products in the European Community" is to be read as a reference to those guidelines.
Paragraph (6) of the Introduction and general principles	The reference to "the requirements of Commission Directive 91/356/EEC laying down the principles of and guidelines of Good Manufacturing Practice for medicinal products for human use" is to be read as a reference to the Good Manufacturing Practice Directive, as defined in regulation 8(1) of the Human Medicines Regulations 2012.
Paragraph (6) of the Introduction and general principles	If the licensing authority has published principles and guidelines under regulation C17(1) of the Human Medicines Regulations 2012, the reference to "the principles and guidelines on GMP published by the

Provision of Annex I	*Modification subject to which that provision is to be read*
	Commission in the rules governing medicinal products in the European Community, Volume 4" is to be read as a reference to those principles and guidelines.
Paragraph (8) of the Introduction and general principles	References to "the European Community" are to be read as references to the United Kingdom.
Paragraph (8) of the Introduction and general principles	The references to "Directive 2001/20/EC of the European Parliament and of the Council on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use" are to be read as references to the Medicinal Products for Human Use (Clinical Trials) Regulations 2004(**1**).
Paragraph (9) of the Introduction and general principles	The reference to "Council Directives 87/18/EEC on the harmonisation of regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their application for tests in chemical substances and 88/320/EEC on the inspection and verification of good laboratory practice" is to be read as a reference to the Good Laboratory Practice Regulations 1999(**2**).
Paragraph (10) of the Introduction and general principles	The reference to "Council Directive 86/609/EEC of 24 November 1986 on the approximation of laws, regulation and administrative provisions of the Member States regarding the protection of animals for experimental and other scientific purposes" is to be read as a reference to the Animals (Scientific Procedures) Act 1986(**3**).
Paragraph (11) of the Introduction and general principles	The paragraph is to be read as follows: "In order to monitor the benefit/risk assessment, any new information not in the original application and all pharmacovigilance information shall be submitted to the licensing authority. After a marketing authorisation has been granted, any change to the data in the dossier shall be submitted to the licensing authority in accordance with the requirements of Schedule 10A to the Human Medicines

(**1**) S.I. 2004/1157.
(**2**) S.I. 1999/3106.
(**3**) 1986 c. 14, as amended by S.I. 2012/3039.

Provision of Annex I	*Modification subject to which that provision is to be read*
	Regulations 2012, as well as the requirements of Schedule 12A to those Regulations."
Part I, paragraph 1.2, fourth paragraph	This paragraph is to be read as follows: "Annexed to the administrative data shall be copies of the manufacturing authorisation as defined in regulation 17 of the Human Medicines Regulations 2012."
Part I, paragraph 1.3.1	The reference to "Article 11" is to be read as a reference to Part 2 of Schedule 8 to the Human Medicines Regulations 2012.
Part I, paragraph 1.3.2	The reference to "Title V" is to be read as a reference to Part I3 of the Human Medicines Regulations 2012, and the references to Articles 63 and 59 are to be read as references to regulations 260 and 266 of the Human Medicines Regulations 2012.
Part I, paragraph 1.3.4	This paragraph is to be read as omitted.
Part I, paragraph 1.4	The reference to "Article 12.2" is to be read as a reference to paragraph 11 of Schedule 8 to the Human Medicines Regulations 2012.
Part I, paragraph 2, first paragraph	The reference to "Article 12" is to be read as a reference to paragraph 11 of Schedule 8 to the Human Medicines Regulations 2012.
Part I, paragraph 3.2(5), first paragraph	The reference to a "Member State" is to be read as including the United Kingdom.
Part I, paragraph 3.2(5), second paragraph	The references to "the national pharmacopoeia of a Member State" are to be read as including references to the British Pharmacopoeia.
Part I, paragraph 3.2(6)	The reference to "the pharmacopoeia of a Member State" is to be read as including a reference to the British Pharmacopoeia.
Part I, paragraph 3.2(12)	The words "which is required by Community legislation" are to be read as omitted.
Part I, paragraph 3.2.1.2	If the licensing authority has published guidelines under regulation 50(5B)(c) of the Human Medicines Regulations 2012, the reference to "guidelines published by the Agency" is to be read as a reference to those guidelines.
Part I, paragraph 3.2.2.1, second paragraph	The reference to "Article 8(3)(c)" is to be read as a reference to paragraph 3 of Schedule 8 to the Human Medicines Regulations 2012.

Provision of Annex I	*Modification subject to which that provision is to be read*
Part I, paragraph 3.2.2.1, second paragraph, first indent	The reference to "the national pharmacopoeia of one of the Member States" is to be read as including the British Pharmacopoeia.
Part I, paragraph 3.2.2.1, fifth paragraph	The reference to "any Member State" is to be read as a reference to the United Kingdom and the reference to "the Member States" is to be read as a reference to the United Kingdom.
Part I, paragraph 3.2.2.3(a)	The reference to "Article 8(3)(d)" is to be read as a reference to paragraph 5 of Schedule 8 to the Human Medicines Regulations 2012.
Part I, paragraph 4.2.2, fifth paragraph	The reference to "this Directive" is to be read as a reference to the Human Medicines Regulations 2012.
Part I, paragraph 5.2(a)	The reference to "the clinical particulars provided pursuant to Articles 8(3)(i) and 10(1)" is to be read as a reference to those particulars provided pursuant to paragraph 10 of Schedule 8 to, and regulations 51 to 56 of, the Human Medicines Regulations 2012.
Part I, paragraph 5.2(c)	The references to "the European Community" are to be read as references to the United Kingdom.
Part I, paragraph 5.2(c), fifth paragraph	The reference to "Directive 2001/20/EC and implementing detail guidelines" is to be read as a reference to the Medicinal Products for Human Use (Clinical Trials) Regulations 2004(**4**).
Part I, paragraph 5.2.1, second paragraph	The reference to "Article 10(1)(a)" is to be read as a reference to regulation 51 of the Human Medicines Regulations 2012.
Part II, paragraph 1, first paragraph	The reference to "Article 10(1)(a)(ii)" is to be read as a reference to regulation 54 of the Human Medicines Regulations 2012.
Part II, paragraph 2(a)	The reference to "Article 10(1)(a)(i)" is to be read as a reference to regulation 56 of the Human Medicines Regulations 2012.
Part II, paragraph 2(b)	The reference to "Article 10(1)(a)(ii)" is to be read as a reference to regulation 51 of the Human Medicines Regulations 2012.
Part II, paragraph 4, first paragraph	The first sentence is to be read as omitted and the words "in accordance with regulation 53 of the Human Medicines Regulations 2012" are

(**4**) S.I. 2004/1157.

Provision of Annex I	*Modification subject to which that provision is to be read*
	to be read as added at the end of the second sentence.
Part II, paragraph 5, first paragraph	The reference to "Article 10(1)(b)" is to be read as a reference to regulation 55 of the Human Medicines Regulations 2012.
Part II, paragraph 6, first paragraph	The reference to "Article 22" is to be read as a reference to regulation 60 of the Human Medicines Regulations 2012.
Part III, paragraph 1.1(a), first indent	The reference to "Directive 2000/70/EC of the European Parliament and of the Council of 16 November 2000 amending Council Directive 93/42/EC as regards medical devices incorporating stable derivatives of human blood or blood plasma" is to be read as a reference to the Medical Devices Regulations 2002(**5**).
Part III, paragraph 1.1(a), third indent	The reference to "the Agency or the competent authority" is to be read as a reference to the licensing authority.
Part III, paragraph 1.1(a), fourth indent	This indent is to be read as omitted.
Part III, paragraph 1.1(b)	The reference to "Article 109, as amended by Directive 2002/98/EC" is to be read as a reference to the Blood Safety and Quality Regulations 2005(**6**).
Part III, paragraph 1.1(b)(3), second paragraph	The reference to "medicinal products referred to in Article 2 of Directive 2001/20/EC of the European Parliament and of the Council relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use" is to be read as a reference to investigational medicinal products.
Part III, paragraph 1.1.(c), second indent	This indent is to be read as follows: "The Plasma Master File is subject to a scientific and technical evaluation by the licensing authority."
Part III, paragraph 1.1(c), fourth indent	This indent is to be read as follows: "Changes subsequently introduced to the terms of a Plasma Master File must follow the variation procedure in Schedule 10A to the Human Medicines Regulations 2012."
Part III, paragraph 1.1(c), final indent	This indent is to be read as omitted.

(**5**) S.I. 2002/618.
(**6**) S.I. 2005/50.

Provision of Annex I	*Modification subject to which that provision is to be read*
Part III, paragraph 1.2(c), first indent	The references to "a competent authority" and to "the Agency" are to be read as references to the licensing authority and the final two sentences are to be read as omitted.
Part III, paragraph 1.2(c), second indent	The reference to "the Community" is to be read as a reference to the United Kingdom.
Part III, paragraph 1.2(c), third indent	This indent is to be read as follows: "Changes in the content of a Vaccine Antigen Master File must follow the variation procedure in Schedule 10A to the Human Medicines Regulations 2012."
Part III, paragraph 1.2(c), fourth indent	This indent is to be read as omitted.
Part III, paragraph 1.2(c), fifth indent	This indent is to be read as omitted.
Part III, paragraph 2.1	The reference to "applications based on Articles 6(2) and 9" is to be read as a reference to applications in relation to radionuclide generators, radionuclide kits, radionuclide precursors and radiopharmaceuticals.
Part III, paragraph 2.2, fourth paragraph	The reference to "Council Directives 87/18/EEC and 88/320/EEC" is to be read as a reference to the Good Laboratory Practice Regulations 1999(**7**).
Part III, paragraph 3, second paragraph	The reference to "Article 15" is to be read as a reference to regulation 103 of the Human Medicines Regulations 2012, the reference to "Article 14(1)" is to be read as a reference to regulation 102 of the Human Medicines Regulations 2012 and the words "referred to in Article 16(1)" are to be read as "which are not registerable homoeopathic medicinal products".
Part III, paragraph 3(a)	The reference to "an official pharmacopoeia of a Member State" is to be read as including the British Pharmacopoeia and any pharmacopoeia used officially in a country that is included in a list published by the licensing authority for that purpose, and the reference to "the traditional names used in each Member State" is to be read as including the traditional name used in the United Kingdom.
Part III, paragraph 3(b), final paragraph	The reference to "an official pharmacopoeia of a Member State" is to be read as including the British Pharmacopoeia.

(7) S.I. 1999/3106.

Provision of Annex I	*Modification subject to which that provision is to be read*
Part III, paragraph 3, penultimate paragraph	The reference to "Article 14(1)" is to be read as a reference to regulation 102 of the Human Medicines Regulations 2012.
Part III, paragraph 5, first indent	The reference to "an orphan medicinal product in the meaning of Regulation (EC) No 141/2000" is to be read as a reference to a medicinal product to which the orphan criteria are claimed to apply.
Part III, paragraph 5, second indent	The reference to "Article 10(1)(a)(ii)" is to be read as a reference to regulation 54 of the Human Medicines Regulations 2012 and the reference to "Article 5" is to be read as a reference to regulation 167 of the Human Medicines Regulations 2012.
Part IV, paragraph 1, first paragraph	The reference to "point (a) of Article 2(1) of Regulation (EC) No 1394/2007" is to be read as a reference to regulation 2A of the Human Medicines Regulations 2012.
Part IV, paragraph 2	This paragraph is to be read as omitted.
Part IV, paragraph 3.1, second paragraph	The reference to "Directive 2004/23/EC" is to be read as a reference to the Human Fertilisation and Embryology Act 1990(**8**) and the Human Tissue (Quality and Safety for Human Application) Regulations 2007(**9**) and the reference to "Directive 2002/98/EC" is to be read as a reference to the Blood Safety and Quality Regulations 2005(**10**).
Part IV, paragraph 3.3.2.1(a)	The reference to "Directive 2004/23/EC" is to be read as a reference to the Human Fertilisation and Embryology Act 1990 and the Human Tissue (Quality and Safety for Human Application) Regulations 2007.
Part IV, paragraph 3.4.1, heading	The reference to "devices as referred to in Article 7 of Regulation (EC) No 1394/2007" is to be read as a reference to medical devices, bio-materials, scaffolds or matrices.
Part IV, paragraph 3.4.2, heading	The reference to "Article 2(1)(d) of Regulation (EC) No 1394/2007" is to be read as a reference to regulation 2A(10) of the Human Medicines Regulations 2012.

(**8**) 1990 c. 37.
(**9**) S.I. 2007/1523.
(**10**) S.I. 2005/50.

Provision of Annex I	*Modification subject to which that provision is to be read*
Part IV, paragraph 3.4.2(c)	The reference to "Commission Directive 2003/32/EC" is to be read as a reference to the Medical Devices Regulations 2002.
Part IV, paragraph 3.4.2(d)	The reference to "Directive 93/42/EEC or Directive 90/385/EEC" is to be read as a reference to the Medical Devices Regulations 2002(**11**).
Part IV, paragraph 3.4.2, final paragraph	The first sentence is to be read as follows: "The applicant shall make available on request of the licensing authority any information related to the assessment by the notified body which has carried out the assessment referred to in point (d) of this section."".

(**11**) S.I. 2002/618.