SCHEDULE 3

Insertion of new Schedule 2A (modifications of Commission Directive 2003/94/EC)

1. After Schedule 2 to the Human Medicines Regulations 2012, insert—

"SCHEDULE 2A Regulations 8(1) and B17(3)

Modifications of Commission Directive 2003/94/EC

Provision of Commission Directive 2003/94/EC	*Modification subject to which that provision is to be read*
Article 1 (scope)	The reference to— (a) "Article 40 of Directive 2001/83/EC" is to be read as a reference to "regulation 17 of the Human Medicines Regulations 2012"; and (b) "Article 13 of Directive 2001/20/EC" is to be read as a reference to "regulation 36 of the Medicines for Human Use (Clinical Trials) Regulations 2004".
Article 2 (definitions)	In the definition of— (a) "medicinal product", the reference to "Article 1(2) of Directive 2001/83/EC" is to be read as a reference to "regulation 2 of the Human Medicines Regulations 2012"; (b) "investigational medicinal product", the reference to "Article 2(d) of Directive 2001/20/EC" is to be read as a reference to "regulation 2(1) of the Medicines for Human Use (Clinical Trials) Regulations 2004"; (c) "manufacturer" the reference to "Article 40(1) and (3) of Directive 2001/83/EC or the authorisation referred to in Article 13(1) of Directive 2001/20/EC" is to be read as a reference to "regulation 17(1) of the Human Medicines Regulations 2012 or the authorisation referred to in regulation 36(1) of the Medicines for Human Use (Clinical Trials) Regulations 2004"; (d) "qualified person" the reference to "Article 48 of Directive 2001/83/EC or in Article 13(2) of Directive 2001/20/EC" is to be read as a reference to "regulation 41 of the Human Medicines Regulations 2012 or regulation 43 of the Medicines for Human Use (Clinical Trials) Regulations 2004".

Provision of Commission Directive 2003/94/EC	*Modification subject to which that provision is to be read*
Article 3(1) (inspections)	The reference to— (a) "for Article 111(1) of Directive 2001/83/EC" is to be read as a reference to "Part 16 of the Human Medicines Regulations 2012 (enforcement)"; (b) "Article 15(1) of Directive 2001/20/EC" is to be read as a reference to "Part 8 of the Medicines for Human Use (Clinical Trials) Regulations 2004 (enforcement)"; (c) "the Member States", is to be read as a reference to "the licensing authority"; (d) "Member States shall" is to be read as a reference to "The licensing authority may"; (e) "published by the Commission, of Community procedures on inspections and exchanges of information" is to be read as if after it there were inserted "or any guidance published by the licensing authority to replace that Commission guidance".
Article 3(2) (inspections)	The reference to— (a) "competent authorities" is to be read as a reference to "licensing authority"; (b) "the second paragraph of Article 47 of Directive 2001/83/EC" to the end is to be read as a reference to "regulation C17(1)(a) of the Human Medicines Regulations 2012, or which applies by virtue of regulation C17(2) of those Regulations".
Article 4(2) (conformity with good manufacturing practice)	The reference to— (a) "third countries" is to be read as a reference to "country other than the United Kingdom"; (b) "Community" is to be read as a reference to "licensing authority".
Article 5 (compliance with marketing authorisation)	The reference to— (a) "Article 9(2) of Directive 2001/20/EC" in both places it appears is to be read as a reference to "regulation 17 of the Medicines

Provision of Commission Directive 2003/94/EC	*Modification subject to which that provision is to be read*
	for Human Use (Clinical Trials) Regulations 2004"; (b) "competent authorities" in both places it appears is to be read as a reference to "licensing authority".
Article 9 (documentation)	The reference in— (a) paragraph (1) to "Article 51(3) of Directive 2001/83/EC" is to be read as a reference to "paragraph 15(1) of Schedule 7 to the Human Medicines Regulations 2012"; (b) paragraph (2) to "competent authorities" is to be read as a reference to "licensing authority".
Article 11 (quality control)	The reference in paragraph (2)— (a) to "point (b) of Article 20 of Directive 2001/83/EC" is to be read as a reference to "paragraph 3 or 17 of Schedule 4 to the Human Medicines Regulations 2012"; (b) to "Article 9(2) of Directive 2001/20/EC" is to be read as a reference to "regulation 17 of the Medicines for Human Use (Clinical Trials) Regulations 2004"; The reference in paragraph (4)— (a) to "Member State" is to be read as a reference to "United Kingdom"; (b) to "competent authority" is to be read as a reference to "licensing authority";
Article 12(4) (work contracted out)	The reference to— (a) "competent authorities" is to be read as a reference to "licensing authority"; (b) "for Article 111 of Directive 2001/83/EC and Article 15(1) of Directive 2001/20/EC" is to be read as a reference to "Part 16 of the Human Medicines Regulations 2012 or Part 8 of the Medicines for Human Use (Clinical Trials) Regulations 2004".
Article 13 (complaints, product recall and emergency unblinding)	The reference to "Article 123 of Directive 2001/83/EC" is to be read as a reference to

Provision of Commission Directive 2003/94/EC	*Modification subject to which that provision is to be read*
	"Part 5 of the Human Medicines Regulations 2012"."