PART B

SECTION I: THE APPLICABLE LAWS, REGULATIONS AND ADMINISTRATIVE PROVISIONS STIPULATING MEDICINAL PRODUCTS, GMP REQUIREMENTS FOR MEDICINAL PRODUCTS, VERIFICATION AND CONFIRMATION

THE UNITED KINGDOM	JAPAN
The Human Medicines Regulations 2012 (SI 2012/1916) and amendments thereto	1. Law concerning Securing Quality, Efficacy and Safety of Products including Pharmaceuticals and Medical Devices (Law No. 145 of 1960) and amendments thereto 2. Cabinet Order for Enforcement of the Law concerning Securing Quality, Efficacy and Safety of Products including Pharmaceuticals and Medical Devices (Cabinet Order No. 11 of 1961) and amendments thereto 3. Regulation for Enforcement of the Law concerning Securing Quality, Efficacy and Safety of Products including Pharmaceuticals and Medical Devices (Ministerial Ordinance of Ministry of Health and Welfare No. 1 of 1961) and amendments thereto

THE UNITED KINGDOM	JAPAN
	4. The Notice on Pharmaceuticals Designated by the Minister for Health, Labour and Welfare under the Provisions of Subparagraphs 6 and 7 of Paragraph 1 of Article 20 of the Cabinet Order for Enforcement of the Law concerning Securing Quality, Efficacy and Safety of Products including Pharmaceuticals and Medical Devices, and under the Provisions of Subparagraphs 6 and 7 of Article 96 of the Regulation for Enforcement of the Law concerning Securing Quality, Efficacy and Safety of Products including Pharmaceuticals and Medical Devices (Notice of Ministry of Health, Labour and Welfare No. 431 of 2004) and amendments thereto 5. Ordinance concerning Facilities and Equipments for Pharmacies Etc. (Ministerial Ordinance of Ministry of Health and Welfare No. 2 of 1961) and amendments thereto