THE UNITED KINGDOM	JAPAN
	(d) Regarding Implementation of the Ministerial Ordinance to Amend a Part of the Ordinance on Industrial Safety and Health, Ministerial Ordinance to Amend a Part of the Ordinance on Safety of Boiler and High Pressure Vessels and the Ministerial Ordinance to Amend a Part of the Ordinance on Preventing Organic Solvents Poisoning, Etc. (Kihatsu No. 602 of 1988) and amendments thereto (e) Regarding Establishment of the Guideline of Certification of Compliance of Test Facilities Etc. with GLP under the Industrial Safety and Health Law (Kihatsu No. 123 of 1989) and amendments thereto

SECTORAL ANNEX ON
GOOD MANUFACTURING PRACTICE (GMP) FOR MEDICINAL PRODUCTS

PART A

1. This Sectoral Annex applies to:

(a) the confirmation of the compliance with GMP requirements of manufacturing facilities for medicinal products to which the GMP requirements of both Parties are applied in accordance with the laws, regulations and administrative provisions of each Party specified in Section I of Part B of this Sectoral Annex; and

(b) the acceptance of the data generated by confirmed manufacturing facilities (the certificate issued by confirmed manufacturing facilities in accordance with the provisions of Part A of this Sectoral Annex).

2.(a) For the purposes of this Sectoral Annex:

(i) "criteria for confirmation" means the GMP requirements;

(ii) "Good Manufacturing Practice (GMP)" means that part of quality assurance which ensures that products are consistently produced and controlled in accordance with the quality standards appropriate for their intended use and as required by the applicable marketing authorisation or product specifications;

(iii) "inspection" means an on-site evaluation of a manufacturing facility to determine whether such manufacturing facility is operating in compliance with GMP requirements including the requirements of the applicable marketing authorisation or product specifications. Such inspection is conducted in accordance with the laws, regulations and administrative provisions specified in Section I of Part B of this Sectoral Annex carried out by a Competent Authority listed in Section II of Part B of this Sectoral Annex, and may include pre-marketing and post-marketing inspection; and