

**Corrections for The Pharmaceutical Affairs Law, Enforcement Ordinance
and Enforcement Regulations 2005/07**

(as of February 9, 2009)

**Change the provision of Article 12, Paragraph 2 of the Pharmaceutical Affairs Law
(see page 9) to read:**

2. The license specified in Paragraph 1 shall become invalid unless it is renewed during a period of not less than 3 years specified by the government ordinance.

**Change the provision of Article 13, Paragraph 3 of the Pharmaceutical Affairs Law
(see page 9) to read:**

3. The license specified in Paragraph 1 shall become invalid unless it is renewed during a period of not less than 3 years specified by the government ordinance.

**Change the provision of Article 14, Paragraph 6 of the Pharmaceutical Affairs Law
(see page 13) to read:**

6. A person intending to obtain the approval specified in Paragraph 1 or a person obtaining the approval specified the same paragraph shall, with respect to the drugs, quasi-drugs, cosmetics or medical devices specified by MHLW Ministerial Ordinance, be subjected to an examination in writing or an on-site examination performed by the Minister as to whether a method of manufacturing control or quality control of it in the manufacturing establishment complies with the standards specified by MHLW Ministerial Ordinance during a period specified by the government ordinance of not less than 3 years after obtaining the approval.

**Change the provision of Article 23-2, Paragraph 3 of the Pharmaceutical Affairs Law
(see page 28) to read:**

3. When a person who intends to obtain the certification specified in Paragraph 1 or a person who obtains the certification in the same paragraph, with respect to the designated controlled medical devices etc. in the certification specified by the government ordinance, intends to obtain the certification of whether a method of manufacturing control and quality control of the product complies with the standards specified by MHLW Ministerial Ordinance pursuant to the provisions of

Article 14, Paragraph 2, Item 4, she/he shall be subjected to an examination in writing or an on-site examination by the third party certification body during a period of not less than 3 years specified by the government ordinance from the date of the certification.

Change the provision of Article 23-6, Paragraph 2 of the Pharmaceutical Affairs Law (see page 30) to read:

2. The registration specified in the preceding paragraph shall become invalid unless it is renewed during a period specified by the government ordinance of not less than 3 years.

Change the provision of Article 40-2, Paragraph 3 of the Pharmaceutical Affairs Law (see page 42) to read:

3. The license specified in Paragraph 1 shall become invalid unless it is renewed during a period specified by the government ordinance of not less than 3 years.

Change the provision of Article 80, Paragraph 1 of the Pharmaceutical Affairs Law (see page 76 to 77) to read:

Article 80 When a manufacturer of drugs, quasi-drugs, cosmetics or medical devices for export intends to manufacture a drug, quasi-drug, cosmetics or medical device specified by the government ordinance, she/he shall be subjected to an examination in writing or an on-site examination of the Minister as to whether methods of manufacturing control and quality control of such product in the manufacturing establishment comply with the standards specified by MHLW Ministerial Ordinance, prior to manufacturing and when a period specified by the government ordinance of not less than 3 years has passed from the date of the commencement of the manufacturer.