Procedure for Reporting Severe Adverse Reactions to Medicines

(Amended Date: 2004-08-31)

Article 1 This set of Regulations is formulated in accordance with regulations of Article 45-1 of the Pharmaceutical Affairs Act (hereafter referred to as the Act).

Article 2 The medicines mentioned in this set of Regulations refer to the medicines mentioned in Article 4 of the Act.

Article 3 When severe adverse reactions are caused by medicines, medical care institutions, pharmacies, and pharmaceutical dealers shall, in accordance with this set of Regulations, fill out a report and submit it, along with any other relevant documents, to the central competent health authority or its commissioned agencies.

Article 4 The severe adverse reactions mentioned in this set of Regulations refer to one of the conditions of the following subparagraphs:

1. Death;
2. Endangerment of life;
3. Resulting in permanent disabilities;
4. Congenital anomalies of fetus and infants;
5. Resulting in hospitalization of patients or extension of patients' hospital stay;
6. Other conditions that may result in permanent

injuries requiring treatment.

Article 5 Medical care institutions and pharmacies shall, within seven days upon knowing of the severe adverse reactions of medicines mentioned in Subparagraph 1 and Subparagraph 2 of the preceding Paragraph, make report in accordance with regulations of Article 3, copy to pharmaceutical dealers holding permit licenses of medicines.

If information of the report mentioned in the preceding Paragraph is not complete, it should be supplied within fifteen days.

If the information of the report mentioned in the preceding Paragraph requires pharmaceutical dealers holding permit licenses of medicines to provide information relevant to the products, pharmaceutical dealers may not refuse.

Article 6 Pharmaceutical dealers holding permit licenses of medicines shall, within fifteen days upon knowing of the severe adverse reactions of medicines, make report in accordance with regulations of Article 3.

Article 7 Medical care institutions, pharmacies, and pharmaceutical dealers reporting in accordance with this set of Regulations may do so by mail, fax, or the Internet.

The reporting of the preceding Paragraph may, in emergency situations, be made orally initially; a report in writing shall be submitted within the time limit.

Article 8 The central competent health authority or its commissioned agencies may, when necessary, ask medical care institutions, pharmacies, and

pharmaceutical dealers for medical records of patients with severe adverse reactions of medicines, records of the medicines administered, or information of the products. Medical care institutions, pharmacies, and pharmaceutical dealers may not refuse.

Article 9 This set of Regulations is implemented on the day of announcement.