Article Content

Title Regulations for Drug Safety Monitoring Ch

Amended Date 2013.11.21

Category Ministry of Health and Welfare (衛生福利部)

Article 1 This set of Regulations is formulated in accordance with regulations of Paragraph 2, Article 45 of the Pharmaceutical Affairs Act.

Article 2 This set of Regulations applies to the following:
1. New medicines mentioned in Article 7 of the Pharmaceutical Affairs Act;
2. Medical devices designated by announcement of the Ministry of Health and Welfare, Republic of China (hereafter referred to as the Ministry);
3. Medicines designated to have a risk management plan by announcement or approval of the Ministry;
4. Medicines designated to have a post marketing clinical trial by the approval of the Ministry;
5. Other cases deemed applicable by announcement of the Ministry.

Article 3 The safety monitoring period of each medicament mentioned in the preceding Article as follows:
1. The period of Subparagraph 1 shall be five years from the date of the issuance of licenses;
2. The period of Subparagraph 2 shall be three years from the date of the issuance of licenses;
3. The period of Subparagraph 3 and 4 shall be approved or announced by the Ministry;
4. The period of Subparagraph 5 shall be announced by the Ministry.
The monitoring period mentioned in the preceding paragraph may be extended by the Ministry if necessary.

Article 4 The manufacturer or importer of the medicament mentioned in the Subparagraph 1, 2 and 5 of Article 2 shall collect its safety information on drug use available both domestically and abroad during the safety monitoring period. In addition to making report following the Regulations Governing the Reporting of Severe Adverse Reactions of Medicines, periodic safety update report shall be fulfilled according to the format announced by the Ministry and submitted to the Ministry within the specified time period.
The manufacturer or importer of the medicine mentioned in the Subparagraph 3 of Article 2 shall conduct announced or approved risk management plan, and submit the tracking reports to the Ministry within the specified time period.
The manufacturer or importer of the medicine mentioned in the Subparagraph 4 of Article 2 shall submit the clinical trial report to the Ministry within the specified time period.
If personal information for the reports mention in the preceding three paragraphs need to be collected and processed by the firms, the personal information shall be collected, processed and used according to Medical Care Act, Personal Information and Protection Act and its related provisions.

Article 5 For new drugs that have completed clinical trials or bridging studies in country and have been approved by the Ministry, during the period of safety monitoring of new drugs, medical care institutions may not ask for the clinical trials or trial use of individual drug. This regulation does not apply to the laboratory testing for acceptance of products.

Article 6　This set of Regulations shall be implemented on the day of announcement.