Article Content

Title Regulations for Publication of Drug Information Ch

Amended Date 2012.07.31

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

Article 1 These regulations are enacted pursuant to the Paragraph 2 of Article 40-1 of the Pharmaceutical Affairs Act.

Article 2 The central competent health authority may, if necessary, publicize summary of assessment reports of drug approvals, and the data below which are submitted by pharmaceutical firms in their application for registration, holding and keeping by the authority. The health authority shall keep confidential for any trade secrets in the new drug applications:
1. ingredient and instruction of the drug.
2. summary of clinical trial protocols.
3. information of drug risk management plan and drug safety.

Article 3 The central competent health authority shall publicize the registration data of medicinal product by following methods:
1. Publish on government bulletin or other publications.
2. Transmit through telecommunications networks or by other ways to provide the public for online search.
3. Any other possible ways of which the information can be made available to the public.

Article 4 These Regulations shall come into force on the date of promulgation.