Announcement of the State Drug Administration on Issuing the "Pharmacological Vi Quality Management Standards" (No. 65 of 2021)

Article source: Releas

According to the "Drug Administration Law of the People's Republic of China" and the "Vaccine Administration Law of the People's Repu in order to regulate and guide the pharmacovigilance activities of drug marketing authorization holders and drug registration applicants, the Drug Administration has organized and formulated the "Pharmacovigilance Quality Management The Regulations are hereby announced, an matters concerning the implementation of the "Pharmacological Vigilance Quality Management Regulations" are announced as follows:

1. The "Pharmacological Alert Quality Management Regulations" will be officially implemented on December 1, 2021.

2. Drug marketing authorization holders and drug registration applicants shall actively prepare for the implementation of the "Pharmaco Vigilance Quality Management Standards", establish and continuously improve the pharmacovigilance system as required, and standardize t of pharmacovigilance activities.

3. The drug marketing authorization holder shall complete the information registration in the National Adverse Drug Reaction Monitorin 60 days from the date of this announcement.

4. Each provincial drug regulatory authority shall urge the drug marketing license holders in their administrative area to actively prepare publicity, implementation and interpretation, and supervise and guide drug marketing licenses through strengthening routine inspections an The holder implements the "Pharmacological Vigilance Quality Management Regulations" as required, and collects and feeds back related iss opinions in a timely manner.

5. The National Adverse Drug Reaction Monitoring Center uniformly organizes and coordinates the publicity, training and technical guid "Pharmacological Vigilance Quality Management Practices", and opens up the "Pharmacological Alert Quality Management Practices" colum website to answer related questions and opinions in a timely manner.

Special announcement.

Attachment: Pharmacovigilance Quality Management Practice

National Food and Drug

Annex to Announcement No. 65 of 2021 of the National Medical Products Administration.doc