

III. DRUG REGISTRATION REGULATIONS

A. Drug Registration Policy

The latest *Administrative Provisions for Drug Registration* was promulgated on June 18, 2007 by the SFDA (Order No. 28) and became effective on October 1, 2007. These Provisions replaced the previous version of the regulation, SFDA Order 17.

B. Classification of Drugs

In China, drugs are classified as 3 types: Chemical Drugs, Biological Drugs, or Traditional Chinese Medicine/Natural Drugs.

For chemical drug registrations, there are 6 different classes:

1. A new drug which has never been marketed in any country.
2. A new drug preparation which changes the administration route¹ of the marketed drug, and has not been marketed anywhere in the world in this form.
3. A new drug which is already marketed outside of China, but has not been marketed in China.
4. A new drug which changes the acid or alkali (or metal) radical of a product marketed in China, but does not change the pharmacological effect.
5. A new drug preparation which has a different dosage form from drugs already marketed in China, but does not change the administration route.
6. Drugs that have already established national specifications in China (generics).

For therapeutic biological product registration, there are 15 different classes:

1. A new biological product which not been marketed before in any country.
2. Monoclonal antibody.
3. Gene therapy, somatic cell therapy, and their preparations.
4. Allergen preparation.
5. Multi-component bioactive products extracted from human and/or animal tissues and/or body fluid, or by fermentation.

¹ Administration route means how the drug is taken such as orally, topically, or through injection.