

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.

6. A combination drug preparation which consists of biological products that are already marketed in China.
7. A drug currently marketed outside of China, but has not been marketed in China.
8. Microbial drug preparations which are produced from cell strains that are not yet approved.
9. A drug preparation with a changed structure from an already-marketed product, where this changed new preparation has not been marketed anywhere around the world (changes include chemical modification, amino acid locus mutation or absence, different expression system, etc.)
10. Drug preparation with different manufacturing processes from an already marketed product (different host cells, expression system, etc.)
11. A drug preparation made for the first time with DNA recombination technology.
12. A new drug preparation with a changed administration route from a marketed product, such as non-injection vs. injection or topical vs. systemic administration, where the new preparation is not marketed anywhere in the world.
13. A new drug preparation which has a different dosage form from a drug already marketed in China, but the same administration route.
14. A new preparation with changes in the administration route from a marketed product, but not including cases falling into class 12.
15. Drugs that have already established national specification in China (generics).

For preventive biological product registration (vaccines), there are 15 different classes:

1. A vaccine not currently marketed domestically or overseas.
2. A DNA vaccine.
3. A currently marketed vaccine with a new drug-enhancing agent (adjuvant) or a changed carrier for a combined vaccine.
4. An unpurified vaccine or full cell vaccine (bacteria, virus) changed into a purified vaccine, or combined vaccine.
5. A vaccine with strains not yet approved in China (except for vaccines for influenza, leptospirosis, etc.).
6. A vaccine already marketed overseas but not yet marketed in China.