appendix

Work plan for chemical drug registration classification reform

In order to encourage the creation of new drugs, strict review and approval, improve drug quality, and promote Industrial upgrading, reform of the current chemical drug registration classification, and specially formulated this work Make plans.

1. Adjustment of chemical drug registration classification categories

The classification categories for chemical drug registration are adjusted, and new registration categories for chemical drugs are divided into The category is divided into 5 categories, as follows:

Category 1: Innovative drugs that have not been marketed domestically or overseas. Refers to a new structure that contains a clear, Compounds with pharmacological effects and drugs with clinical value.

Category 2: Improved new drugs that are not marketed domestically or overseas. Refers to known active ingredients On the basis of the dosage, its structure, dosage form, prescription process, route of administration, adaptability Drugs that are optimized for certain diseases and have obvious clinical advantages.

Category 3: Domestic applicants copy original drugs that are marketed overseas but not marketed domestically. of medicines. Such drugs should be of the same quality and efficacy as the original drugs.

Original research drugs refer to the first domestically and overseas approved drugs that are approved for marketing and have complete and sufficient Drugs whose safety and effectiveness data serve as the basis for marketing.

Category 4: Domestic applicants imitate drugs that have been marketed in the country as original research drugs. Such drugs should be of the same quality and efficacy as the original drugs.

Category 5: Drugs marketed overseas apply to be marketed domestically.

Table 1 Classification, description and inclusion of newly registered chemicals

register Classification	Classification description	Included situations
1	Not available at home or abroad city's innovative drugs	Contains new structurally clear compounds with pharmacological effects and clinical value value of raw materials and preparations.
2	Not listed at home or abroad improved new drugs	2.1 Optically heterogeneous compounds containing known active ingredients prepared by resolution or synthesis. conformation, either to form esters of known active ingredients, or to form salts of known active ingredients (including including salts containing hydrogen or coordination bonds), or acids that alter the active ingredients of known salts roots, bases or metal elements, or form other non-covalent derivatives (such as complex substances, chelates or inclusion compounds) and have obvious clinical advantages and their preparations.
		2.2 New dosage forms (including new drug delivery systems) and new prescriptions containing known active ingredients process, new administration routes, and preparations with obvious clinical advantages.
		2.3 New compound preparations containing known active ingredients and having obvious clinical advantages.
		2.4 Preparations containing known active ingredients for new indications.
3	Imitation overseas listing But it is not listed in China original drug Goods	Have the same active ingredients, dosage forms, specifications, indications, and administration as the original drug Route, usage and dosage of raw materials and preparations.
4	Imitation has been released in China Municipal original research drugs drug	Have the same active ingredients, dosage forms, specifications, indications, and administration as the original drug Route, usage and dosage of raw materials and preparations.
5	Drugs marketed overseas Product application within the country Listed	5.1 Application for domestic listing of original research drugs (including raw materials and preparations) marketed overseas city.
		5.2 Application for non-original drugs (including raw materials and preparations) marketed overseas to be made domestically Listed.

Note: 1. "Known active ingredients" refers to "active ingredients of marketed drugs".

2. Registration classification 2.3 does not include "new compound preparations containing unknown active ingredients".

2. Relevant registration management requirements

(1) The review and approval of new drugs shall be based on the material basis of originality and novelty.

Basically, the requirements for clinical value are emphasized, among which the requirements for improved new drugs are higher than those for improved

It has obvious clinical advantages. Review and approval of generic drugs emphasizes cooperation with original research

Consistency of drug quality and efficacy.

(2) Newly registered drugs in categories 1 and 2 shall be registered in accordance with the "Drug Registration Administration"

Procedures for declaration of new drugs in the Regulations; newly registered Class 3 and 4 drugs,

Apply according to the procedures for generic drugs in the "Measures for the Administration of Drug Registration"; new registrations are divided into

Category 5 drugs, according to the procedures for imported drugs in the "Drug Registration Management Measures"

Order declaration.

For newly registered drugs in Category 2 that meet the requirements of multiple situations at the same time,

This must be stated in the application form.

(3) According to the "Regulations on the Implementation of the Drug Administration Law of the People's Republic of China"

Relevant requirements require a 3-5 year monitoring period for new drugs, as follows:

Table 2 Monitoring Period Schedule for New Chemical Drugs

Register category	Monitoring period duration
1	5 years
2.1	3 years
2.2	4 years
2.3	4 years
2.4	3 years

(4) Chemical drug registration applications that have been accepted before the issuance and implementation of this plan,

You can continue to review and approve in accordance with the original regulations, or you can apply for new registration

Classification for review and approval. If the application is reviewed and approved according to the new registration classification,

After paying the relevant fees, no additional technical data will be required. The National Food and Drug Administration

The Drug Evaluation Center of the State Council should establish a green channel to speed up review and approval. conform to

If the requirements are met, the listing will be approved; if the requirements are not met, no additional information will be required until the

Acceptance is not approved.

(5) Drug approval number issued by the registration application for the new registration category

(Imported Drug Registration Certificate/Pharmaceutical Product Registration Certificate) The validity is the same as the original registration classification

Drug approval number issued by registration application (imported drug registration certificate/pharmaceutical product

Registration Certificate) has the same effect.

(6) The State Food and Drug Administration organizes relevant departments to refine

Work requirements, do a good job in acceptance, verification and inspection, technical review, formulation and revision

Relevant national drug standards and other work.

(7) If the "Measures for the Administration of Drug Registration" are inconsistent with this plan, the

This plan requires implementation.