Annex 3

Priority Review and Approval Procedures for Drug Marketing Authorization (Trial)

In order to encourage the research and creation of new drugs, standardize the priority review and approval of drugs that are urgently needed in clinical practice, etc., in accordance with the Drug Administration Law of the People's Republic of China, the Traditional Chinese Medicine Law of the People's Republic of China, the Vaccine Administration Law of the People's Republic of China, and the People's Republic of China This work procedure is formulated in accordance with relevant regulations such as the Implementation Regulations of the Drug Administration Law and the Measures for the Administration of Drug Registration.

1. Scope of application

When applying for drug marketing authorization, the following drugs with obvious clinical value can be The application is subject to the priority review and approval process:

(1) urgently needed drugs in short supply, innovative drugs and improved new drugs for the prevention and treatment of major infectious diseases and rare diseases; (2) new varieties, dosage forms and specifications of children's drugs that meet the physiological characteristics of children; (3) disease prevention, Control urgently needed vaccines and innovative vaccines; (4) Drugs included in the breakthrough therapy drug program; (5) Drugs that meet the conditions for approval; (6) Other priority review and approval situations stipulated by the State Drug Administration.

2. Applicable conditions

If the application is subject to the priority review and approval procedure, it should satisfy (1) and (2) at the same time:

(1) Drug marketing authorization applications that meet the scope of priority review and approval shall have

Obvious clinical value, refer to the applicable conditions of clinical advantages in the "Breakthrough Therapy Drug Review Work Procedures (Trial)". (2) Drug marketing authorization applications that meet the scope of priority review and approval, with the following

The scope of application should meet the relevant conditions:

1. Shortage of medicines that are urgently needed in clinical practice. The urgently needed drugs in shortage shall be included in the "National List of Drugs in Shortage" issued by the National Health Commission and other departments, and shall be determined by the State Drug Administration.

For generic drug applications for urgently needed drugs in short supply, from the date when the first company is included in the priority review and approval process, priority review and approval applications for new applications with the same active ingredient and route of administration will no longer be accepted.

2. Innovative drugs and improved new drugs for the prevention and treatment of major infectious diseases and rare diseases. Major infectious diseases should be identified by the National Health Commission, rare diseases should be included in the list of rare diseases jointly issued by the National Health Commission and other departments, and the drug should have obvious clinical value.

3. New varieties, dosage forms and specifications of children's medicines that meet the physiological characteristics of children.

(1) For new varieties, one of the following conditions should be met: ÿ For diseases that seriously threaten the life of children or affect the growth and development of children, and there is currently no effective drug or treatment; ÿ Compared with existing drugs on the market, it has obvious therapeutic advantages ;

(2) For a new dosage form, the following two conditions should be met at the same time: ÿ The drug insert of the existing marketed dosage form contains clear information on indications for children and the usage and dosage for children; ÿ The existing marketed dosage form is not suitable for children, and the new dosage form is not suitable for children. The dosage form is suitable for children;

(3) For the new specification, the following two conditions shall be satisfied at the same time: ÿ The existing

The market-specific drug insert contains clear indications for children and information on the usage and dosage of children; ÿ The existing marketed specifications are not suitable for children, and the new specifications are suitable for children;

In addition, according to the "List of Children's Drugs Encouraged for Research and Development" and other documents issued by the National Health Commission and other departments, priority review and approval will be implemented for children's drugs that are clearly in short supply in the market and are encouraged to be submitted for research and development.

4. Vaccines and innovative vaccines urgently needed for disease prevention and control. The specific list of vaccines urgently needed for disease prevention and control is proposed by the National Health Commission and the Ministry of Industry and Information Technology, and determined by the State Drug Administration.

5. Other situations of priority review and approval stipulated by the State Drug Administration will be announced separately. Among them, for rare disease drugs listed in the State Drug Administration's "List of Overseas New Drugs Urgently Needed in Clinical" by the State Drug Administration, which are marketed overseas but not yet marketed in China, the applicant may apply for drug marketing authorization according to the scope of application "(VI) National Drug Administration The Administration stipulates other circumstances for priority review and approval" to submit an application for priority review and approval.

3. Working procedure

(1) Communication before application. Before submitting an application for a drug marketing authorization, the applicant shall communicate with the Center for Drug Evaluation of the State Drug Administration (hereinafter referred to as the Center for Drug Evaluation) to discuss whether the existing research data meets the requirements for drug marketing authorization review and whether it is eligible for priority review. The conditions for inclusion in the examination and approval procedures, etc., should be specified in the meeting minutes if the preliminary assessment finds that the conditions for inclusion in the priority review and approval are met. The Center for Drug Evaluation may, as needed, participate in the participation of relevant personnel from drug inspection agencies and the Center for Food and Drug Review and Inspection of the State Drug Administration (hereinafter referred to as the Center for Drug Inspection).

Communication and exchange meetings before the application are held to jointly negotiate and solve existing technical problems, inspection and verification problems, and provide support for subsequent review and approval. When necessary, the Center for Drug Evaluation may organize an expert advisory committee to demonstrate whether it meets the conditions for inclusion in the priority review and approval process.

(2) Reporting and filing applications. After communication and confirmation, the applicant should submit an application for priority review and approval through the website of the Center for Drug Evaluation at the same time as the application for drug marketing authorization, and submit relevant supporting materials (Appendix 1). The relevant supporting materials submitted by the applicant on the website of the Center for Drug Evaluation shall be consistent with the content of the application materials.

(3) Review. The Center for Drug Evaluation shall review the submitted application for priority review and approval within 5 days after receiving the application, and report the review results back to the applicant. Those that are to be included in the priority review and approval procedure shall be announced on the website of the Center for Drug Evaluation as required.

For rare disease drugs that are listed in the "List of Overseas New Drugs in Urgent Clinical Need" of the State Drug Administration, the drugs for rare diseases that have been marketed overseas but have not been marketed in China will be directly included in the priority review and approval process after being accepted by the Center for Drug Evaluation, and will not be announced to the public.

(4) Public notice included. The Center for Drug Evaluation will publicize the specific information and reasons for the products to be included in the priority review and approval process, including the name of the drug, the applicant, the proposed indication (or main function), the date of application, and the reason for the proposed inclusion. If there is no objection within 5 days of publicity, it will be included in the priority review and approval process, and all relevant parties will be notified; if there is any objection to the publicized variety, a written opinion should be submitted to the Center for Drug Evaluation and the reasons within 5 days (Annex 2); Within 10 days, a decision will be made after a separate demonstration and the relevant parties will be notified. When necessary, the Center for Drug Evaluation may organize an expert advisory committee to conduct demonstrations.

(5) Termination of the procedure. For varieties included in the priority review and approval process, the applicant

When it is found that it no longer meets the conditions for inclusion, it shall promptly submit a request to the Center for Drug Evaluation to terminate the priority review and approval procedure; if the Center for Drug Evaluation finds that it no longer meets the conditions for inclusion, it shall notify the applicant, and the applicant may submit a written request to the Center for Drug Evaluation within 10 days. Description, the Center for Drug Evaluation will organize the demonstration and notify the applicant after the decision is made within 30 days. If the applicant fails to submit a written statement to the Center for Drug Evaluation within 10 days, or if it is decided that it does not meet the inclusion conditions after demonstration, the Center for Drug Evaluation shall promptly terminate the priority review and approval procedure for the product. The Center for Drug Evaluation will publicly list the varieties included in the priority review and approval process, update the variety status information (including inclusion and termination information), record the varieties newly included in the program in a timely manner, and identify the varieties that have been terminated from the program.

(6) Technical review. The Center for Drug Evaluation shall prioritize the allocation of resources for the review of drug marketing authorization applications included in the priority review and approval process according to the time sequence of registration application acceptance. For drug marketing authorization applications included in the priority review and approval process, the review time limit is 130 days, of which the review time limit for rare disease drugs that are urgently needed overseas and that have not been marketed in China is 70 days.

If the Center for Drug Evaluation finds that it is necessary to communicate with the applicant during the review, it can be prioritized according to the specific situation.

(7) Verification, inspection and approval of common names. For the drug marketing authorization application included in the priority review and approval process, if it is necessary to check, test and approve the generic name, the Drug Inspection Center, the Drug Testing Institute and the State Pharmacopoeia Commission shall give priority to the verification, inspection and approval of the generic name. For the drug marketing authorization application applying for the priority review and approval process, if the applicant does not submit a drug registration test before the drug registration application is accepted, the Center for Drug Evaluation shall conduct the drug registration test.

An inspection notice will be issued within 2 days after the registration application is accepted, and a preliminary review will be conducted within 25 days after the acceptance. If a drug registration inspection is required, the Drug Inspection Center shall be notified to organize the inspection, provide the relevant materials required for the inspection, and inform the applicant and the applicant or The drug administration department of the province, autonomous region or municipality directly under the Central Government where the production enterprise is located. The drug inspection center and drug inspection institution shall complete the inspection and inspection work 25 days before the expiration of the review time limit, and feed back the inspection situation, inspection results, standard review opinions and inspection report and other relevant materials to the drug evaluation center.

For rare disease drugs that are listed in the "List of Overseas New Drugs in Urgent Clinical Need" of the State Drug Administration, and the applicant has not submitted a drug registration test before the acceptance of the drug registration application, the Center for Drug Evaluation shall accept the drug before the acceptance. The inspection notice shall be issued within 2 days after the registration application, and the drug inspection agency shall be notified at the same time. The drug inspection agency shall complete the inspection work 15 days before the expiration of the review time limit, and feedback the standard review opinions and inspection report to the Center for Drug Evaluation. After the State Drug Administration has completed the marketing approval, it can carry out drug registration verification according to the needs of technical review.

(8) After communication and confirmation, supplementary technical materials are submitted. For the drug marketing authorization application included in the priority review and approval process, during the review process, the applicant may submit a communication application for supplementary submission of technical information through the website of the Center for Drug Evaluation. After communication and confirmation, the applicant can submit the corresponding technical materials as required, and the review time limit will not be extended. If the applicant fails to submit as required, the Center for Drug Evaluation shall make an evaluation conclusion based on the existing evaluation materials. (9) Comprehensive review. After receiving the verification results, test results, etc.

After the materials are closed, the comprehensive review will be completed within the review time limit.

(10) Approval. The administrative approval decision shall be made within 10 days.

4. Job requirements

(1) The Center for Drug Evaluation shall communicate with the applicant for the varieties included in the priority review and approval process in accordance with the "Administrative Measures for Communication and Exchange of Drug Research and Development and Technical Review", "Administrative Specifications for Consultation on General Technical Issues in Drug Registration Review" and other relevant regulations comminicate.

(2) Before submitting an application for priority review and approval, the application materials shall comply with the relevant technical guidelines and acceptance requirements, and be prepared to accept drug registration verification and inspection at any time. If there is a problem with the authenticity of the application materials, it shall be handled in accordance with the relevant provisions of the "Administrative Measures for Drug Registration".

(3) During the technical review process, if it is found that the application materials of the varieties included in the priority review and approval process cannot meet the requirements for priority review and approval, the Center for Drug Evaluation will terminate the priority review of the variety and review according to the normal review procedures. The review time limit was adjusted, and the Center for Drug Inspection, the Drug Inspection Agency and the State Pharmacopoeia Committee were informed that the verification, inspection and approval of generic names would no longer be prioritized.

The time limit stipulated in this work procedure is calculated in working days. This working procedure will be implemented from the date of publication.

Attachment: 1. Application Form for Priority Review and Approval of Drug Marketing Authorization

2. Objection form for drug marketing authorization priority review and approval variety

Attached 1

Application Form for Priority Review and Approval of Drug Marketing Authorization

Drug Name			
applicant			
Communication before filing meeting number			
Type of medicine		registration classification	
Indications (or main function)			
eligible for priority review Approval situation			
Reason for Application	Describe specific terms that qualify for priority review and approval, and discuss The priority review approval situation and applicable conditions are explained in detail, Relevant supporting materials and basis can be submitted together as attachments.		

Attachment 2

Drug Listing Authorization Priority Review and Approval Variety Objection Form

proposer	(can be unit or individual)
employer	
contact details	
Disputed drug marketing authorization information	
Drug Name	
Acceptance number (If there is)	
Company Name	
priority review There are objections to the review and approval reason	The objection to the priority review and approval of the variety should be explained in detail. The reasons and relevant basis can be submitted as attachments together:
unit signature or person signing	year month day Note: If the proposer is a unit, the unit shall sign and seal; if the proposer is an individual, it shall be signed by the individual Character.