Procedures for the Review and Approval of Applications for Conditional Marketing Authorization of Pharmaceutical Products[1]

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To encourage pharmaceutical innovation driven by clinical value and to expedite the marketing authorization of urgently needed drugs with significant clinical value, these Procedures are formulated in accordance with the Drug Administration Law of the People's Republic of China, the Law of the People's Republic of China on Traditional Chinese Medicine, the Vaccine Administration Law of the People's Republic of China, the Regulations for the Implementation of the Drug Administration Law of the People's Republic of China, the Measures for the Administration of Drug Registration, and other relevant laws and regulations.

I. Eligibility Criteria

Applicants may apply to the Center for Drug Evaluation of the National Medical Products Administration (hereinafter referred to as the "CDE") for conditional marketing authorization during the conduct of drug clinical trials or human experience studies, provided that the drug concerned satisfies the circumstances and requirements for conditional approval set forth in the Measures for the Administration of Drug Registration, the Technical Guidelines for Conditional Approval of Drugs (Trial), the Special Provisions on the Registration Administration of Traditional Chinese Medicines, and other relevant provisions governing traditional Chinese medicines. In particular:

(1) Drugs urgently needed for public health purposes shall be proposed by the competent national health authorities and other relevant governmental departments.

(2) Vaccines urgently needed in response to major public health emergencies shall refer to preventive vaccines for diseases associated with a Major Public Health Emergency (Level II) or an Extraordinary Major Public Health Emergency (Level I), as determined in accordance with the Emergency Response Law of the People's Republic of China, the Regulations on Emergency Response to Public Health Emergencies, the National Emergency Response Plan for Public Health Emergencies, and other applicable provisions.

[1]Translated by Health Law Asia – Pharmaceutical, Medical Device, and Cosmetics Law

II. Procedures

(1) Early Communication and Consultation

Applicants are encouraged, during the course of drug clinical trials and following adequate assessment, to communicate with the Center for Drug Evaluation ("CDE") regarding the clinical development plan for conditional marketing authorization, the design of pivotal clinical trials and selection of efficacy endpoints, other prerequisites for conditional approval, and the preliminary design and implementation plan for confirmatory studies, in accordance with the requirements of relevant technical guidelines.

(2) Communication and Consultation Prior to Submission of a Marketing Authorization Application

Where an applicant intends to apply for conditional marketing authorization, it shall, prior to the submission of the marketing authorization application, communicate with the CDE regarding the conditions for conditional approval, the progress of confirmatory studies, the anticipated completion date thereof, and other studies to be conducted after marketing authorization.

Where the applicant intends to apply for priority review and approval, such request may be raised during the communication and consultation process. Upon obtaining agreement, the applicant may submit an application for priority review and approval in accordance with the Procedures for Priority Review and Approval of Drug Marketing Authorization Applications (Trial) and other relevant provisions.

(3) Submission of an Application for Conditional Marketing Authorization

Where communication and consultation indicate that the drug preliminarily satisfies the requirements for conditional marketing authorization, the applicant may, concurrently with the submission of the marketing authorization application, submit the Application Form for Conditional Marketing Authorization of Drugs and provide supporting documentation in accordance with the requirements of relevant technical guidelines.

(4) Review and Approval of Applications for Conditional Marketing Authorization

Where an application passes technical review and, in cases where conditional marketing authorization is supported by early clinical trial data, documentary evidence demonstrating the initiation of confirmatory studies has been submitted (with the signing of the informed consent form by the first study participant serving as the criterion for study initiation), conditional marketing authorization shall be granted and a Drug Registration Certificate shall be issued.

The Drug Registration Certificate shall specify, among other things, its validity period, the post-marketing studies to be completed, and the time limits for their completion. The completion period shall be calculated from the date of conditional marketing authorization and, in principle, shall not exceed four years. The validity period of the Drug Registration Certificate shall be

determined based on the time required for completion of the confirmatory studies and the review process.

Where technical review determines that the requirements for conditional marketing authorization have not been met, or where documentary evidence demonstrating the initiation of confirmatory studies has not been received before the conclusion of the review process, a decision of non-approval shall be issued and a Notice of Disapproval of the Drug Registration Application shall be served.

The applicant may, upon completion of the relevant studies, resubmit the application under the ordinary approval procedure.

In accordance with the Drug Administration Law, the Measures for the Administration of Drug Registration, and the Technical Guidelines for Conditional Approval of Drugs (Trial), once a drug has obtained regular marketing approval, other similar drugs that are under development or under review will no longer meet the requirements for conditional marketing authorization.

Where, during the review of an application for conditional marketing authorization, the applicant completes the confirmatory study, it may apply to the CDE for conversion to the regular approval review pathway and submit the confirmatory study data. Where the CDE determines upon evaluation that the relevant requirements are satisfied, the conditional approval review procedure shall be terminated and the application shall proceed under the regular approval review procedure.

(5) Post-Marketing Confirmatory Studies

Following the grant of conditional marketing authorization, the provincial drug regulatory authority shall supervise the marketing authorization holder ("MAH") or its domestic responsible person in implementing appropriate risk management measures and completing, within the prescribed timeframe, the confirmatory studies specified in the Drug Registration Certificate.

From the date of conditional marketing authorization and throughout the development period, the MAH shall submit an annual report on the progress of the confirmatory studies to the CDE, together with the periodic safety update report. A copy of the progress report shall simultaneously be submitted to the provincial drug regulatory authority in the locality where the MAH or its domestic responsible person is located.

During the conduct of confirmatory studies, where amendments to the clinical trial protocol or other changes may increase risks to study participants, the MAH shall promptly submit a supplemental application in accordance with the relevant requirements.

Where, due to objective circumstances, a confirmatory clinical trial cannot be conducted as originally planned and a change to the study protocol is therefore required, the MAH may request communication and consultation with the CDE. Upon reaching agreement with the CDE, the MAH shall submit a clinical trial application in accordance with the relevant requirements.

Following approval upon review by the CDE, the confirmatory study plan and the corresponding study timeline shall be redetermined, while the validity period of the Drug Registration Certificate shall remain unchanged.

Where the CDE does not agree to the proposed amendment, the MAH shall complete the confirmatory study in accordance with the original study protocol.

Where the MAH is unable to complete the confirmatory study within the prescribed timeframe, it shall, prior to the expiry of the study period, submit a supplemental application to the CDE requesting an extension. Where the application is approved upon review, the holder may continue the study, and a revised deadline for completion shall be specified. The validity period of the Drug Registration Certificate shall remain unchanged. Upon expiry of the certificate, the information relating to the relevant indication shall be removed from the package insert and labeling, where the product has multiple approved indications.

As a general principle, no more than one extension application may be granted. For vaccines urgently needed in response to major public health emergencies, where the confirmatory study cannot be completed on schedule due to force majeure circumstances such as changes in the epidemiological situation, a further extension application may be permitted.

(6) Regular Approval

Prior to the expiry of the study period, the MAH shall timely submit a supplemental application requesting conversion from conditional marketing authorization to regular approval.

Where the confirmatory study data submitted by the MAH demonstrate that the benefits of the drug outweigh its risks, and the application is approved upon review, a Notice of Approval of the Supplemental Application shall be issued, and the validity period of the Drug Registration Certificate shall be adjusted accordingly.

Where the confirmatory study data submitted by the marketing authorization holder fail to demonstrate that the benefits of the drug outweigh its risks, the CDE shall issue a negative review conclusion and a Notice of Disapproval of the Supplemental Application.

Where the completed clinical study also supports the approval of a new indication, the MAH may submit an application for marketing authorization of the new indication and, within the same application, request the conversion of the conditionally approved indication to regular approval. In such circumstances, no separate supplemental application shall be required.

(7) Cancellation of the Drug Registration Certificate

Where the validity period of the Drug Registration Certificate expires and the application for extension of the confirmatory study is not approved, or where, upon expiry of the extended study period, the MAH fails to submit an application for conversion to regular approval as required, the National Medical Products Administration ("NMPA") shall, in accordance with the prescribed procedures, cancel the Drug Registration Certificate if the product has only one

approved indication; where other approved indications remain, the relevant indication shall be removed from the product labeling and package insert.

Where the confirmatory study data submitted by the MAH fail to pass technical review, the NMPA shall, in accordance with applicable procedures, cancel the Drug Registration Certificate or remove the relevant indication(s).

Where the MAH voluntarily terminates or completes the confirmatory study and, based on its own assessment, determines that the study results are insufficient to confirm the safety and efficacy of the product, it shall immediately cease the sale of the relevant indication, promptly report the relevant circumstances to the CDE, and apply for cancellation of the Drug Registration Certificate or removal of the relevant indication(s).

During the confirmatory study period, where the CDE identifies and confirms that the available evidence is insufficient to demonstrate that the benefits outweigh the risks, the NMPA may, in accordance with applicable procedures, cancel the Drug Registration Certificate or remove the relevant indication(s).

III. Requirements

(1) Communication and engagement during the process of conditional marketing approval applications shall be conducted in accordance with the *Administrative Measures for Communication and Exchange on Drug R&D and Technical Review*, and other applicable provisions. Following approval, communications during confirmatory studies may refer to the pre-marketing communication requirements under the same Measures.

(2) Prior to submission of an application for conditional marketing approval, applicants shall ensure that submission materials comply with relevant technical guidelines and acceptance requirements, and shall be prepared for regulatory inspection and testing related to drug registration.

(3) The technical requirements for the review and approval of conditional marketing applications shall be implemented in accordance with the *Technical Guideline for Conditional Approval of Drugs (Trial)* and other applicable provisions. During the review process (including evaluation of confirmatory studies), expert opinions may be solicited on major issues to fully leverage technical expert support.

(4) During the conditional approval period, if the marketing authorization holder completes confirmatory studies significantly earlier than the originally specified timeline, the holder shall promptly submit a supplemental application or an application for additional indications upon obtaining the study results.

(5) For drugs granted conditional approval, prior to conversion to standard approval, such products shall generally not be designated as reference listed drugs. Where an applicant for a generic drug is able to independently conduct confirmatory studies without reliance on

originator data, it may apply for marketing authorization under the relevant generic drug registration category.

(6) For drugs/indications granted conditional approval, renewal applications shall, in principle, only be submitted after completion of confirmatory studies and conversion to standard approval.

(7) Following conditional approval, information regarding the product, including the drug name, marketing authorization holder, conditionally approved indications, and timelines for completion of confirmatory studies, shall be disclosed to the public and updated in a timely manner.

(8) In the event of a proposed transfer of marketing authorization for a conditionally approved drug, the transferee shall thoroughly assess existing safety and efficacy data and ensure complete transfer of prior research, as well as timely completion of confirmatory studies. Prior to submitting the transfer application, the transferee shall engage in communication with the Center for Drug Evaluation regarding study progress and future research plans; only upon agreement through such communication may the transfer application be formally submitted.

(9) For medicines and vaccines urgently needed in response to major public health emergencies, as well as other special products, requirements for confirmatory studies and regulatory management may be assessed in a comprehensive manner, taking into account objective circumstances such as force majeure events, medical practice, and clinical needs.

This procedure shall enter into force as of the date of issuance.