Administrative Provisions on Changes to the Registered Entities of Chemical Active Pharmaceutical Ingredients (Draft for Comments)[1]

Authorities: **NMPA**

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Chapter I General Provisions

Article 1 (Legislative Basis)

For the purposes of further improving the administration of chemical active pharmaceutical ingredients, regulating changes to registered entities, facilitating the entry into the market of a greater number of higher-quality and compliant manufacturing entities, and promoting the high-quality development of the chemical active pharmaceutical ingredient industry, these Provisions are formulated pursuant to the Drug Administration Law of the People's Republic of China, the Regulation for the Implementation of the Drug Administration Law of the People's Republic of China, the Drug Registration Regulation, the Measures for the Supervision and Administration of Drug Manufacturing, and other relevant laws, administrative regulations and rules.

Article 2 (Definition and Scope of Application)

A change of the registered entity of a chemical active pharmaceutical ingredient refers to a change of the manufacturing enterprise specified in the approval certificate of a chemical active pharmaceutical ingredient that has been registered on the Active Pharmaceutical Ingredient, Pharmaceutical Excipients and Pharmaceutical Packaging Materials Registration Platform of the Center for Drug Evaluation of the National Medical Products Administration (hereinafter referred to as the "CDE"), and which is designated as "A", whereby the manufacturing enterprise after such change (hereinafter referred to as the "Transferee") assumes responsibility as the registered entity and obtains approval to independently manufacture the chemical active pharmaceutical ingredient concerned.

The application, review, approval and supervision and administration of changes to the registered entities of chemical active pharmaceutical ingredients shall be governed by these Provisions.

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

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Article 3 (Implementing Authorities)

The CDE shall be responsible for the acceptance, review and approval of applications for changes to the registered entities of chemical active pharmaceutical ingredients, as well as any accompanying changes to manufacturing sites and, where applicable, technical changes arising in the course of changes to manufacturing sites.

The provincial-level drug regulatory authority at the place where the Transferee is located shall be responsible for issuing the drug manufacturing licence for changes to the registered entity of a domestically manufactured chemical active pharmaceutical ingredient, as well as for conducting registration testing and inspections.

Article 4 Responsibilities and Requirements)

The Transferor shall fully transfer to the Transferee all technical documentation relating to the chemical active pharmaceutical ingredient and shall actively cooperate with and provide guidance to the Transferee in completing the technology transfer, change management and other related activities.

As the party responsible for risk management in connection with a change of the registered entity of a chemical active pharmaceutical ingredient, the Transferee shall acquire a comprehensive understanding of the API's development history, manufacturing characteristics and critical quality attributes. Taking into account the characteristics of the product and in accordance with the applicable laws and regulations governing drug administration, as well as the relevant requirements concerning drug registration and manufacturing, the Transferee shall implement change-related risk management, assess the impact of the change on the quality system, manufacturing processes and quality standards, conduct adequate research and evaluation and, where necessary, validation, and implement the change only after obtaining approval in accordance with the applicable requirements, so as to ensure the Transferee's ability to continuously and consistently manufacture the product independently in compliance with its intended use and registration requirements.

Article 5 (Information Notification Obligations)

The Transferor and the Transferee shall fulfil their respective obligations to notify the Marketing Authorization Holder of the relevant drug product. The Transferor shall promptly notify the relevant Marketing Authorization Holder of the proposed transfer, while the Transferee shall promptly provide such notification upon approval of the transfer, informing the relevant Marketing Authorization Holder of the change in the registered entity. The Marketing Authorization Holder of the relevant drug product shall assess the impact of the change to the

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active pharmaceutical ingredient on the drug product, conduct the necessary research and validation in accordance with the relevant guidelines, and implement the change in accordance with the Measures for the Administration of Post-Marketing Changes to Drugs (for Trial Implementation).

Chapter II Work Procedures

Article 6 (Application for Change of Registered Entity)

An application for a change to the registered entity of a chemical active pharmaceutical ingredient shall be submitted by the Transferee, which shall conduct the relevant research as required, prepare the application materials and submit a supplementary application to the CDE.

Article 7 (Acceptance)

Following submission by the Transferee of an application for a change to the registered entity of the chemical active pharmaceutical ingredient, the CDE shall, within 5 days, make a decision to accept the application, request supplementation or correction of the application materials, or refuse to accept the application.

Article 8 (Changes Involving a Manufacturing Site)

The Transferee shall ensure that it independently manufactures the chemical active pharmaceutical ingredient. Where a change to the manufacturing site is involved in the course of a change to the registered entity of a chemical active pharmaceutical ingredient, the Transferee shall, in accordance with the Measures for the Supervision and Administration of Drug Manufacturing, the Measures for the Administration of Post-Marketing Changes to Drugs (for Trial Implementation), the Technical Guidelines for the Pharmaceutical Research on Changes to Marketed Chemical Drugs (for Trial Implementation), and other applicable requirements, complete adequate research, evaluation and validation, and, upon satisfying the conditions for manufacturing, apply to the provincial-level drug regulatory authority at the place where it is located for the corresponding scope of drug manufacturing authorization. When reviewing the scope of the Transferee's manufacturing authorization, the provincial-level drug regulatory authority shall concurrently conduct the preliminary registration testing and registration inspection of the chemical active pharmaceutical ingredient proposed to be transferred.

Upon completion of the foregoing procedures, the Transferee may submit to the CDE a supplementary application for the change to the registered entity, the accompanying change

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to the manufacturing site, and any technical changes arising in the course of the manufacturing-site change, where applicable.

Article 9 (Approval)

Following acceptance of an application for a change to the registered entity of a chemical active pharmaceutical ingredient, where no change to the manufacturing site is involved (such as a change to the registered entity resulting from a corporate merger or demerger), the CDE shall complete the approval within 20 working days. Where a change to the manufacturing site is involved, the CDE shall complete the review and approval within the time limit applicable to supplementary applications under the Drug Registration Regulation.

Where the Transferor holds a paper version of the chemical active pharmaceutical ingredient approval certificate, the original certificate shall be submitted to the CDE before the Notice of Approval of the Supplementary Application may be issued to the Transferee.

Article 10 (Publication)

Following completion of the approval of the supplementary application for a change to the registered entity, the CDE shall publish, through the Registration Platform for Active Pharmaceutical Ingredients, Pharmaceutical Excipients and Pharmaceutical Packaging Materials, the information concerning the API following the transfer.

The conclusion of the review and approval of the application for a change to the registered entity shall be promptly copied to the Transferor, the Transferee and the provincial-level drug regulatory authority at the place where each is located.

Article 11 (Post-Marketing Research)

Where the approval of a chemical active pharmaceutical ingredient is subject to post-marketing research requirements and the Transferor has not yet completed the required research, the Transferee shall complete the outstanding post-marketing research in accordance with the applicable requirements.

Chapter III Protection of the Rights and Interests of Entities Responsible for the Development of Innovative Chemical Active Pharmaceutical Ingredients

Article 12 (Registration of Rights and Interests Holders for Innovative Chemical Active Pharmaceutical Ingredients)

When an innovative drug chemical active pharmaceutical ingredient is registered on the Registration Platform for Active Pharmaceutical Ingredients, Pharmaceutical Excipients and Pharmaceutical Packaging Materials, the registrant may, in accordance with the contractual

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arrangements, specify in the remarks field the rights and interests holder of the entity responsible for the development of the chemical active pharmaceutical ingredient (hereinafter, the "Rights and Interests Holder"), which may be the actual entity responsible for its development, the holder of the relevant innovative drug, the holder of the patent rights to the compound, or another relevant entity.

For an innovative drug chemical active pharmaceutical ingredient that has already obtained a registration number, the registrant may submit a supplementary application to the CDE to add or change the Rights and Interests Holder on the Registration Platform for Active Pharmaceutical Ingredients, Pharmaceutical Excipients and Pharmaceutical Packaging Materials.

Article 13 (Protection of the Rights and Interests of Entities Responsible for the Development of Innovative Chemical Active Pharmaceutical Ingredients)

A change to the registered entity of an innovative drug chemical active pharmaceutical ingredient shall be subject to the consent of the Rights and Interests Holder. The Transferee may, on the basis of a transfer agreement entered into with the Rights and Interests Holder, submit an application for a change to the registered entity of the chemical active pharmaceutical ingredient in accordance with these Provisions.

Chapter IV Miscellaneous Provisions

Article 14 (Transfer from Overseas Production to Domestic Production)

Where a chemical active pharmaceutical ingredient manufactured overseas is transferred for manufacturing in China, the domestic chemical active pharmaceutical ingredient manufacturing enterprise shall submit the relevant application in accordance with the applicable requirements governing the marketing of chemical active pharmaceutical ingredients.

Article 15 (Changes to Overseas Registered Entities)

Where a chemical active pharmaceutical ingredient is manufactured overseas and the competent regulatory authority of the relevant foreign jurisdiction has approved a change to the entity holding the relevant certificate, while the actual manufacturing site, manufacturing process, quality standards and other relevant conditions remain unchanged, the overseas registrant shall designate a legal entity within China to submit to the CDE a supplementary application for a change to the registered entity of the chemical active pharmaceutical ingredient, in order to ensure consistency between the registration information in China and the regulatory information in the relevant foreign jurisdiction.

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Article 16 (Anti-Monopoly Measures)

A manufacturing enterprise that already holds an approval certificate for a chemical active pharmaceutical ingredient of the same variety may apply as the Transferee for a change to the registered entity of a chemical active pharmaceutical ingredient of the same variety only after the approval certificate it holds has been cancelled.

Article 17 (Quality Improvement Requirements for Older Products)

Where an application for a change to the registered entity of a chemical active pharmaceutical ingredient approved before the implementation of the latest applicable technical guidelines or the corresponding ICH Guidelines involves a change to the manufacturing site, the chemical active pharmaceutical ingredient shall comply with the latest technical requirements for the review and evaluation of active pharmaceutical ingredients.

Article 18 (Implementation Requirements)

These Provisions shall enter into force XX days after the date of promulgation. The National Medical Products Administration (NMPA) shall be responsible for the interpretation of these Provisions.

Annex - Requirements for Application Materials for Changes to the Registered Entity of Chemical Active Pharmaceutical Ingredients

I. Copies of the Approval Documents for the Chemical Active Pharmaceutical Ingredient and Their Annexes

These shall include copies of all approval documents previously obtained in respect of the chemical active pharmaceutical ingredient for which the application is submitted, including the Marketing Approval Notification for the Chemical Active Pharmaceutical Ingredient, the Approval Notification for a Supplementary Application for the Chemical Active Pharmaceutical Ingredient, and the Re-registration Approval Notification for the Chemical Active Pharmaceutical Ingredient.

The relevant documents shall clearly demonstrate the complete history of the development of the relevant product and its current status.

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II. Supporting Documents

(1) Domestic manufacturing of chemical active pharmaceutical ingredients

Copies of the Drug Manufacturing Licence and the corresponding page recording changes thereto, the Business Licence, and the original Agreement on the Change of the Registered Entity of the Chemical Active Pharmaceutical Ingredient shall be submitted, with any information involving commercial secrets redacted.

The following shall also be provided:

Information concerning the product proposed for transfer, including records of batch release by the Transferor for at least three batches of the product manufactured during the preceding five years, with the relevant records covering a period of more than 36 months; and registration testing reports demonstrating that three batches manufactured by the Transferee under its quality system have passed testing conducted by a provincial-level drug testing institution.

(2) Overseas manufacturing of chemical active pharmaceutical ingredients

Where a chemical active pharmaceutical ingredient is manufactured overseas and the competent regulatory authority of the relevant foreign jurisdiction has approved a change to the holder of the relevant certificate, while the actual manufacturing site, manufacturing process, quality standards and other relevant conditions remain unchanged, and the overseas registrant designates a legal entity within China to handle the relevant drug registration matters in order to ensure consistency between the registration information in China and the regulatory information in the relevant foreign jurisdiction, the following shall be provided:

the power of attorney or other authorization document, together with the relevant notarization and legalization/authentication documents, accompanied by a Chinese translation; and a copy of the business licence of the domestic registration agent in China.

For a chemical active pharmaceutical ingredient manufactured overseas, a supporting document issued by the competent authority of the relevant country or region certifying that the change of the registered entity of the chemical active pharmaceutical ingredient is permitted, together with the relevant notarization and legalization/authentication documents and a Chinese translation thereof, shall be submitted.

(3) Where no change to the manufacturing site is involved, the Transferee shall provide an undertaking confirming that the manufacturing site, manufacturing process, quality standards and other relevant aspects of the chemical active pharmaceutical ingredient proposed to be

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transferred shall remain consistent with those of the original product and shall not be subject to change.

(4) For active pharmaceutical ingredients subject to special regulatory controls by the State, the relevant project establishment approval document shall be obtained.

III. Additional Materials to Be Submitted Where a Change to the Manufacturing Site Is Involved

(1) Information relating to inspection and testing.

This shall include the Drug Development Information Form, the Drug Manufacturing Information Form, the Site Master File List, the registration testing reports demonstrating that three batches of samples manufactured by the Transferee under its quality system have passed testing conducted by a provincial-level drug testing institution, and the registration inspection report.

(2) The revised drug quality standards, Manufacturing Process Information Form, and draft label specimens, together with a detailed explanation of the revisions.

(3) Pharmaceutical research documentation.

Research shall be conducted in accordance with the relevant technical guidelines on pharmaceutical changes to marketed chemical drugs and other applicable technical guidelines issued by the national drug regulatory authority. Depending on the specific requirements applicable to each type of change under the relevant technical guidelines, some or all of the relevant pharmaceutical research study data and literature, as well as the necessary materials from the original registration application, shall be submitted.

IV. Other

Other documents required by the national drug regulatory authority.

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