Announcement of the National Medical Products Administration on Matters Concerning the Application of the Priority Review and Approval Procedures for Drug Marketing Authorization of Chemical Active Pharmaceutical Ingredients [1]

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To further promote the high-quality development of the pharmaceutical industry, enhance the accessibility of medicines, and meet the public's medication needs, the National Medical Products Administration ("NMPA"), in accordance with the requirements of the Drug Registration Regulation and the Working Procedures for Priority Review and Approval of Drug Marketing Authorization Applications (Trial), hereby announces that eligible applications for marketing authorization of chemical active pharmaceutical ingredients (APIs) may apply for the application of the priority review and approval procedures for drug marketing authorization. The relevant matters are hereby announced as follows:

I. Eligibility Criteria for Applying for the Priority Review and Approval Procedure

An application for marketing authorization of a chemical active pharmaceutical ingredient (API) may be submitted for inclusion in the priority review and approval procedure if any of the following circumstances applies:

(1) The chemical API associated with a drug product that has already been included in the priority review and approval procedure in accordance with the *Working Procedures for Priority Review and Approval of Drug Marketing Authorization Applications (Trial)*;

(2) A chemical API that is used in a drug product approved for marketing in China, for which only overseas manufacturing sources are currently available, and for which the applicant is the first domestic manufacturer submitting a marketing authorization application in China and applying for a separate review and approval procedure;

(3) An overseas-manufactured chemical API that is currently supplied for the manufacture of an originator drug product approved for marketing in China, where an application is submitted for

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import marketing authorization in China or for a transfer of manufacturing to a domestic site, and a separate review and approval procedure is requested;

(4) A chemical API for which the relevant competent departments of the State Council have identified a market shortage.

II. Procedures for Inclusion in the Priority Review and Approval Procedure

For the circumstance set forth in Paragraph (1) of Article I of this Announcement, the Center for Drug Evaluation ("CDE") of the National Medical Products Administration ("NMPA") shall, upon review, directly include eligible applications for marketing authorization of chemical active pharmaceutical ingredients (APIs) into the priority review and approval procedure.

For the circumstances set forth in Paragraphs (2) and (3) of Article I of this Announcement, the relevant chemical API registration applicants may access the CDE website of the NMPA to review the relevant information and determine whether the applicable criteria are met. Where the requirements are satisfied, applicants shall, when submitting an application for marketing authorization of a chemical API, submit an application for priority review and approval under item (6), "Other circumstances subject to priority review and approval as prescribed by the NMPA," of the scope of application specified in the *Working Procedures for Priority Review and Approval of Drug Marketing Authorization Applications (Trial)*. A separate application for a communication meeting shall not be required.

The CDE of the NMPA shall conduct review, public announcement, and other relevant procedures in accordance with the *Working Procedures for Priority Review and Approval of Drug Marketing Authorization Applications (Trial)*.

For the circumstance set forth in Paragraph (4) of Article I of this Announcement, upon receipt of a written recommendation from the relevant competent departments of the State Council, the CDE of the NMPA shall, following review, directly include the first chemical API marketing authorization application currently under review or newly submitted application into the priority review and approval procedure.

III. Effective Date

This Announcement shall take effect on August 1, 2026.