Announcement of the 12th National Centralized Volume-Based Procurement of Pharmaceuticals[1]

Authority: **National Joint Office for Centralized Pharmaceutical Procurement**

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To implement the decisions and deployments of the Central Committee of the Communist Party of China and the State Council, and in accordance with the requirements set forth in the Opinions of the Central Committee of the Communist Party of China and the State Council on Deepening the Reform of the Healthcare Security System and the Opinions of the General Office of the State Council on Promoting the Regular and Institutionalized Implementation of Centralized Volume-Based Pharmaceutical Procurement (State Council General Office Document No. 2 [2021]), representatives delegated by all provinces, autonomous regions, municipalities directly under the central government, and the Xinjiang Production and Construction Corps shall constitute the National Joint Office for Centralized Pharmaceutical Procurement (hereinafter "the Joint Office"). The Joint Office shall, on behalf of public medical institutions, military medical institutions, and privately-operated medical and pharmaceutical institutions across all regions, conduct the 12th National Centralized Volume-Based Procurement of Pharmaceuticals. The Shanghai Municipal Office for Centralized Bidding and Procurement of Pharmaceuticals shall assume the routine administrative functions and execute the operational implementation thereof. Pharmaceutical enterprises committed to advancing the health and well-being of the Chinese people are cordially invited to actively participate and contribute to rendering pharmaceuticals more equitable and accessible throughout China. The relevant matters are hereby announced as follows:

I. Procurement Varieties

1.1 The procurement varieties covered by this centralized volume-based procurement are set forth in the Scope of Procurement Varieties.

1.2 With respect to the varieties that were subject to preliminary pre-filing, those that satisfy the criteria of competitive landscape and procurement scale but are not included in this centralized volume-based procurement.

II. Eligibility and Requirements for Application

2.1.1 Domestic marketing authorization holders, foreign marketing authorization holders, and their domestic responsible parties may all participate. For the purposes of this Announcement,

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

"responsible party" shall mean, in accordance with the relevant regulations of the competent national authorities governing domestic responsible parties for foreign marketing authorization holders, a domestic corporate entity designated by a foreign marketing authorization holder to perform the obligations of a marketing authorization holder within the territory of China and to assume joint and several liability with the marketing authorization holder. Where a foreign marketing authorization holder has not designated a domestic responsible party, it may designate a domestic corporate entity within China as its domestic agent to represent it in this centralized volume-based procurement and to perform the obligations of a marketing authorization holder as prescribed by laws and regulations.

2.1.2 Applying undertakings shall comply with all relevant laws and regulations, including but not limited to the Pharmaceutical Administration Law of the People's Republic of China, the Price Law of the People's Republic of China, the Anti-Unfair Competition Law of the People's Republic of China, the Anti-Monopoly Law of the People's Republic of China, and the Patent Law of the People's Republic of China, and shall bear the corresponding legal liabilities.

2.1.3 Neither the applying undertaking nor its entrusted manufacturing enterprise shall have been included on the current "List of Defaulters" maintained by the Joint Office. Where an applying undertaking has acquired the subject pharmaceutical product through the transfer of a pharmaceutical registration approval certificate, the transferring entity of the relevant approval certificate must not have been on the current "List of Defaulters" at the time of such transfer (including in cases of multiple transfers).

2.1.4 Where, on or before June 23, 2026, an application for the change of the marketing authorization holder has been submitted to the drug regulatory authority but such change has not yet been completed, the current marketing authorization holder shall participate in the application and, jointly with the transferee undertaking, submit a written undertaking. Both the transferor and the transferee undertakings must satisfy all the conditions set forth under "Eligibility of Undertakings for Application" and "Eligibility of Pharmaceutical Products for Application."

2.2 Eligibility of Pharmaceutical Products for Application

2.2.1 The pharmaceutical product must fall within the scope of procurement varieties and must have obtained a valid domestic registration approval certificate on or before June 23, 2026, and must satisfy one of the following conditions:

2.2.1.1 It is a reference listed drug for generic drugs as published by the national drug regulatory authority (possessing the corresponding approval certificate or available for verification in the Chemical Drug Catalogue of the Center for Drug Evaluation of the National Medical Products Administration; the same shall apply hereinafter);

2.2.1.2 It is a pharmaceutical product that has passed the national drug regulatory authority's consistency evaluation for quality and efficacy of generic drugs;

2.2.1.3 It is a generic pharmaceutical product approved under the chemical drug registration classification pursuant to the Announcement of the China Food and Drug Administration on Issuing the Work Plan for the Reform of Chemical Drug Registration Classification (No. 51 [2016]) or the Notice of the National Medical Products Administration on Issuing the Chemical Drug Registration Classification and Requirements for Application Dossiers (No. 44 [2020]), and has demonstrated consistency in quality and efficacy with the reference listed drug;

2.2.1.4 It is a pharmaceutical product where the reference listed drug, originally manufactured overseas, has been transferred to domestic production and has completed the registration studies in accordance with the relevant regulations of the drug regulatory authority and has been approved for market, and the registration approval certificate or other documents of equivalent legal effect demonstrate the continuity with the original reference listed drug.

2.2.2 Pharmaceutical products satisfying the conditions set forth in section 2.2.1 must concurrently satisfy the following conditions:

2.2.2.1 The marketing authorization holder of the applying pharmaceutical product or its entrusted manufacturing enterprise shall possess manufacturing experience for the same type of formulation and shall provide batch release records or domestic sales documentation for the same type of formulation within the most recent five years (submitting relevant materials for any two time points between June 2021 and June 2026, with a time span between the two materials in excess of 24 months).

2.2.2.2 The applying pharmaceutical product must have passed the pre-market Good Manufacturing Practice (GMP) compliance inspection and shall provide relevant evidentiary materials issued or published by the drug regulatory authority confirming GMP compliance. For imported pharmaceutical products, relevant evidentiary materials from the overseas drug regulatory authority confirming GMP compliance may be provided; provided, however, that for generic drugs manufactured overseas, evidentiary materials demonstrating the completion of GMP inspections conducted by the Chinese drug regulatory authority, including but not limited to inspection reports, shall be provided.

Where the relevant evidentiary materials for GMP compliance inspection of the applying pharmaceutical product are not within their validity period, the results of the most recent GMP compliance inspection for the same type of formulation shall also be provided. Where the relevant evidentiary materials for GMP compliance inspection do not specify the name of the specific pharmaceutical product, an undertaking shall concurrently be made that the applying pharmaceutical product will be manufactured on a production line that has passed GMP compliance inspection, and relevant supporting materials (such as batch production records after approval of the applying pharmaceutical product, statements of explanation, etc.) shall be provided.

2.2.2.3 The production line for the applying pharmaceutical product must have had no instances of non-compliance with GMP requirements within the preceding two years (June 2024 to June 2026). The applying pharmaceutical product must not have had any instance of failure

in production quality inspection by the drug regulatory authority at the provincial level or above within the preceding two years prior to this centralized volume-based procurement activity (with respect to generic drugs involved, this refers to instances occurring after the product was launched following the passing of the national drug regulatory authority's consistency evaluation for quality and efficacy of generic drugs).

2.2.2.4 The applying undertaking shall issue a written Intellectual Property Undertaking. Where an undertaking fails to submit the Intellectual Property Undertaking or fails to make a "Non-Infringement Undertaking" before the application deadline (including undertakings that have already been listed on provincial pharmaceutical procurement platforms but have elected not to apply), the relevant products that are already listed on provincial pharmaceutical procurement platforms shall be delisted. For products that have not yet been listed, as well as those that have been delisted, listing applications shall not be accepted during the term of the agreement, except where the patent expires during the term of the agreement.

2.2.2.5 The applying pharmaceutical product shall apply for and obtain the national healthcare insurance code (23-digit pharmaceutical product code) in a timely manner and shall comply with the policy document requirements of the national drug regulatory authority and the national healthcare security authority regarding pharmaceutical traceability codes.

III. Application Timeline and Procedures

The filing of pharmaceutical product information constitutes a prerequisite step for the volume declaration by medical institutions. Pharmaceutical products for which the information filing has been completed and approved will serve as the scope of selection for the subsequent declaration of demand by medical institutions by brand. Pharmaceutical product brands that have not been approved within the prescribed timeframe shall not be included in the scope of selection for the declaration of demand by medical institutions.

Filing Period: June 23, 2026, 9:00 – June 26, 2026, 16:00.

Period for Amendments or Supplemental Materials: June 23, 2026, 9:00 – June 26, 2026, 18:00.

Varieties that completed the preliminary product information pre-filing during the period of May 15 to May 21, 2026, and have been approved, need not refile. Where the pre-filed information, upon review, requires amendment or supplementation, such materials must be resubmitted prior to the deadline.

3.2 Centralized Procurement Bid Registration

Centralized procurement bid registration is the step by which undertakings, having completed the "Pharmaceutical Product Information Filing" set forth in section 3.1, confirm their intention to participate in this centralized volume-based procurement. Undertakings whose preliminary product information pre-filing has been approved may proceed directly to the registration stage. Only pharmaceutical products for which registration has been completed and approved within

the prescribed timeframe may participate in the bidding for this centralized volume-based procurement. Failure to do so shall be deemed a waiver of participation in the bidding.

Registration Period: June 23, 2026, 9:00 – July 13, 2026, 16:00.

Period for Amendments or Supplemental Materials: June 23, 2026, 9:00 – July 14, 2026, 16:00.

At the time of registration, information regarding pharmaceutical product production capacity and other relevant details must be submitted, with specific requirements to be determined in accordance with the platform's document submission guidelines.

3.3 Application Method

The National Healthcare Security Platform (website: fuwu.nhsa.gov.cn) provides access for relevant undertakings to the channels for pharmaceutical product information filing and centralized procurement bid registration. Upon logging into the platform, undertakings shall select "Pharmaceutical and Medical Device Procurement Services" – "National Centralized Pharmaceutical Procurement Information Filing" – "Enterprise Login" to proceed with the filing. Application materials shall comply with the prescribed format requirements and shall bear the official seal of the undertaking, with specific requirements to be determined in accordance with the platform's document submission guidelines.

New users of the platform shall click "Register" on the login page and complete the required information to establish a platform account. User accounts are valid for the long term and need not be re-registered. Undertakings with existing user accounts shall resubmit or amend the qualification documents relevant to this centralized procurement.

3.4 Materials to be Uploaded

Pharmaceutical product information filing and centralized procurement bid registration materials shall comply with the prescribed format requirements, bear the official seal of the undertaking, and be uploaded through the platform. The specific materials are as follows:

3.4.1 Pharmaceutical product registration approval certificates, reference listed drug documentation, or evidence of passing the consistency evaluation, etc.;

3.4.2 Pharmaceutical product package inserts, outer packaging images, etc.;

3.4.3 Capacity Declaration Letter;

3.4.4 Intellectual Property Undertaking;

3.4.5 Relevant evidentiary materials for GMP compliance inspection, undertakings, etc.;

3.4.6 Batch release records or domestic sales documentation for the same type of formulation within the most recent five years;

3.4.7 Corporate Undertaking for Change of Pharmaceutical Product Registration Approval Certificate;

3.4.8 Other relevant materials.

IV. Important Notices

4.1 Pharmaceutical product brands that are not included in the scope of demand declared by medical institutions may, provided they satisfy the eligibility requirements and complete centralized procurement bid registration within the prescribed timeframe with approval, still participate in the bidding for this centralized volume-based procurement.

4.2 With respect to varieties subject to asserted patent disputes, undertakings shall bear sole responsibility for the intellectual property status of their products. Undertakings that fail to submit the Intellectual Property Undertaking or fail to make a "Non-Infringement Undertaking" prior to the application deadline (including undertakings that have already been listed on provincial platforms but have elected not to apply) shall have their relevant products restricted from listing on provincial platforms. All parties are hereby strongly advised to take this matter with utmost seriousness.

4.3 All undertakings are hereby strongly advised to attach great importance to this matter and to submit information on eligible varieties in a timely manner, so as to avoid omissions or errors that may affect subsequent participation in centralized volume-based procurement and listing on provincial platforms.

4.4 Any other matters not covered herein shall be announced separately. Please remain attentive for further updates.

National Joint Office for Centralized Pharmaceutical Procurement

June 23, 2026