Interpretation of the Announcement on the Public Disclosure of Pharmaceutical Products and Related Information That Have Passed the Preliminary Formal Review for the Adjustment of the National Basic Medical Insurance, Maternity Insurance, and Work-Related Injury Insurance Drug Catalog and the Commercial Health Insurance Innovative Drug Catalog for the Year 2026[1]

Authority: **National Healthcare Security Administration (NHSA)**

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In accordance with the operational arrangements for the adjustment of the National Basic Medical Insurance, Maternity Insurance, and Work-Related Injury Insurance Drug Catalog and the Commercial Health Insurance Innovative Drug Catalog for the year 2026 (hereinafter respectively referred to as the "Basic Medical Insurance Catalog" and the "Commercial Insurance Innovative Drug Catalog"), the National Healthcare Security Administration has recently conducted a preliminary formal review of the declared pharmaceutical products and is now publicly disclosing the list of products that have passed the preliminary review, along with their principal information. The relevant operational matters are hereby interpreted as follows:

I. Function of the formal review

The formal review constitutes an examination as to whether the declared pharmaceutical products satisfy the eligibility criteria for the adjustment of the Basic Medical Insurance Catalog and the Commercial Insurance Innovative Drug Catalog for the current year, as well as a verification of the completeness of the information submitted with each declaration. Pursuant to the Working Plan for the Adjustment of the National Basic Medical Insurance, Maternity Insurance, and Work-Related Injury Insurance Drug Catalog and the Commercial Health Insurance Innovative Drug Catalog for the Year 2026, the formal review procedure comprises four sequential stages: preliminary review, publication of the preliminary review results, re-examination, and announcement of the final results. The content of the present public disclosure corresponds precisely to the preliminary review results for this year.

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

By conducting a formal review of the declaration dossiers for pharmaceutical products, on the one hand, it ensures that the declared products meet the prescribed eligibility conditions; on the other hand, it verifies the completeness and standardization of the declaration materials, thereby facilitating the comprehensiveness, authenticity, and accuracy of information in the subsequent stages of expert evaluation and price estimation (or: pricing assessment). Furthermore, to ensure transparency and openness in the catalog adjustment process, the National Healthcare Security Administration publicly discloses the list of products that have passed the preliminary review together with their core information. This disclosure itself constitutes a proactive means of accepting public oversight, and we welcome all sectors of society to assist us in identifying any issues and to offer valuable comments and suggestions.

II. Does Passing the Preliminary Formal Review Mean That These Pharmaceutical Products Have Been Incorporated into the Basic Medical Insurance Catalog or the Commercial Insurance Innovative Drug Catalog?

Pursuant to the Interim Measures for the Administration of Basic Medical Insurance Drug Use and the Working Plan for the Adjustment of the National Basic Medical Insurance, Maternity Insurance, and Work-Related Injury Insurance Drug Catalog and the Commercial Health Insurance Innovative Drug Catalog for the Year 2026, the catalog adjustment process consists of several stages, including enterprise declaration, formal review, expert evaluation, and negotiation/competitive bidding or price consultation, as applicable. The formal review constitutes merely the first step in the entire catalog adjustment procedure following the enterprise declaration. A pharmaceutical product's passage of the preliminary formal review signifies only that it has satisfied the corresponding eligibility criteria at the preliminary review stage; it remains subject to public disclosure for social oversight. Even if a product is ultimately confirmed to have passed the formal review, this merely establishes its qualification to participate in the subsequent procedural stages of the catalog adjustment process and does not imply that it has been incorporated into the Basic Medical Insurance Catalog or the Commercial Insurance Innovative Drug Catalog.

III. What Is the Overall Status of Enterprise Declarations and Preliminary Formal Review Results for 2026?

From June 1 to June 10, 2026, the National Healthcare Security Administration received a total of 818 declaration submissions for the adjustment of the medical insurance drug catalog, involving 674 generic drug names. Upon preliminary review, among the declared pharmaceutical products that had obtained registration approval documents prior to June 10, 557 passed the preliminary review for the Basic Catalog: of these, 503 declaration submissions pertained to products outside the catalog, involving 375 generic drug names, of which 334 passed the preliminary review; 236 declaration submissions pertained to products within the catalog, involving 229 generic drug names, of which 223 passed the preliminary review. 54

products passed the preliminary review for the Commercial Insurance Innovative Drug Catalog: of these, 57 declaration submissions pertained to products outside the catalog, involving 57 generic names, of which 53 passed the preliminary review; 1 generic name within the catalog passed the preliminary review. Certain pharmaceutical products were declared simultaneously for both the Basic Medical Insurance Catalog and the Commercial Insurance Innovative Drug Catalog; however, because the eligibility criteria for the two catalogs are not entirely identical, inconsistencies may arise between the formal review results for the Basic Medical Insurance Catalog and those for the Commercial Insurance Innovative Drug Catalog.

In addition, 49 generic names (including 2 with concurrent declarations for new indications) submitted pre-declarations for products outside the Basic Catalog, of which 1 manifestly failed to meet the eligibility criteria; 11 generic names already within the Basic Catalog submitted pre-declarations for new indications; and 4 generic names submitted pre-declarations for products outside the Commercial Insurance Innovative Drug Catalog. The enterprises submitting pre-declarations generally provided, as required, webpage screenshots of the review (or: evaluation) progress or relevant supporting documentation. The products subject to pre-declaration on this occasion are also included in the present public disclosure.

IV. How Will the Products That Submitted Pre-Declarations After Completing Technical Evaluation Prior to June 10 Be Processed in the Subsequent Steps?

In order to allow the necessary lead time for implementation following the publication of the catalog and for coordination with commercial insurance, the commencement of the declaration process for this year's catalog has been advanced by one month relative to previous years. With a view to minimizing the impact on the innovative pharmaceutical industry, products that have not yet obtained formal approval at the declaration stage but have already completed technical evaluation (or: review) are permitted to submit pre-declarations. With respect to the products and indications subject to pre-declaration, we have already requested the assistance of the relevant authorities for verification purposes, and the final results will be determined upon review based on the feedback information received. We hereby remind enterprises whose products are subject to pre-declaration that, following the public disclosure of the preliminary formal review results, we will provide feedback and notification information through the system. Should formal approval have been obtained, it is imperative to submit the approval documentation in accordance with the notification information before 17:00 on July 3. Failure to submit within the prescribed time limit or submission of incorrect documentation will be deemed as non-passage (or: failure). Enterprises are requested to monitor the matter in a timely manner. It should be noted that products that did not satisfy the requirement of having completed technical evaluation prior to June 10, but obtained approval and submitted supplementary approval documentation prior to July 3, shall still be deemed ineligible for declaration and will not pass the formal review.

Products that are currently listed as exclusive in the present disclosure may, at the time of the formal announcement, be revised to non-exclusive status as a result of the formal approval of pre-declared products. Enterprises are requested to pay attention to this matter.

V. What Changes Have Occurred in Enterprise Declarations and Preliminary Formal Review Results for 2026 Compared to the Previous Year?

Overall, the products declared this year present several notable characteristics: First, the number of declared products has further increased. This year, a total of 818 declaration dossiers were received, involving 674 generic names, representing an increase of 100 declaration dossiers and 41 generic names compared to 2025. Second, the passage rate for the formal review has substantially improved. Excluding products subject to pre-declaration, the overall passage rate for the preliminary formal review stands at 92%, an increase of 8 percentage points compared to the previous year, indicating that the majority of pharmaceutical enterprises are able to accurately interpret the catalog adjustment work plan and submit declarations in accordance with the prescribed conditions. Third, declared products are predominantly new drugs. The number of products declared under Category 1 for products outside the catalog—namely, new generic-name drugs approved within the preceding five years—amounts to 343 (excluding pre-declared products). Overall, both the number of declared pharmaceutical products and the proportion passing the formal review are higher than in previous years. On the one hand, this reflects the vigorous development of China's pharmaceutical industry, the continued increase in the number of new drugs marketed, and the high level of attention and active participation by pharmaceutical enterprises in the drug catalog adjustment process. On the other hand, it also demonstrates that enterprises have gained a clearer understanding of the catalog adjustment rules and have acted more rationally, as certain products that had previously been declared multiple times without passing the formal review were not submitted again on this occasion.

VI. How Should We View the Fact That Certain Pharmaceutical Products with Relatively High Market Prices, Which Manifestly Exceed the Scope of Basic Coverage, Have Passed the Formal Review for the Basic Medical Insurance Catalog?

Since its establishment, the National Healthcare Security Administration has resolutely implemented the decisions and arrangements of the Central Committee of the Communist Party of China and the State Council, has consistently and firmly adhered to the functional positioning of basic medical insurance as "ensuring basic coverage," has persistently strived to do its utmost within the limits of its capacity, and has determined the scope of coverage on a factual and realistic basis. It has consistently upheld a robust and sustainable approach, taking the affordability of the medical insurance fund and the insured population as the foundation for the adjustment of the Basic Medical Insurance Catalog, and has effectively controlled pharmaceutical expenditures through mechanisms such as access (or: market entry)

negotiations. It has steadfastly focused on maintaining the balance between the basic medical needs of the population and advances in clinical technology, thereby enhancing accessibility and safeguarding equity. The fact that certain pharmaceutical products with relatively high prices, which may potentially exceed the coverage capacity of basic medical insurance, have passed the preliminary formal review for the Basic Medical Insurance Catalog this year signifies only that such products satisfy the declaration eligibility criteria and have obtained the qualification to proceed to the subsequent stage. Whether such products will ultimately be incorporated into the Basic Medical Insurance Catalog remains subject to rigorous expert evaluation, followed by subsequent procedures—including negotiations for exclusive products and competitive bidding for non-exclusive products—before they may be finally included in the Catalog.

VII. What Work Will Be Undertaken Following the Present Public Disclosure?

In the subsequent steps, we will, on the basis of the feedback received during the public disclosure period and the feedback from the relevant authorities, conduct a re-examination of the relevant pharmaceutical product information, determine the final list of products that have passed the formal review, and publicly announce the same. Simultaneously, the final formal review results, whether passed or not, will be communicated to the declaring enterprises through the declaration module for the 2026 adjustment of the Basic Medical Insurance Catalog and the Commercial Insurance Innovative Drug Catalog. The National Healthcare Security Administration will, in accordance with the requirements of the Work Plan, expedite the advancement of expert evaluation, the negotiation and competitive bidding processes for the Basic Medical Insurance Catalog, and the price consultation process for the Commercial Insurance Innovative Drug Catalog.

We express our gratitude to all sectors of society for their concern and support for medical security work.