

Announcement of the National Medical Products Administration on Strengthening the Supervision and Administration of Entrusted Drug Manufacturing¹

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To further strengthen the supervision of entrusted manufacturing of marketed drugs, clarify the obligations and responsibilities of all parties, and urge marketing authorization holders (hereinafter referred to as “holders”) and entrusted manufacturers to jointly fulfil their primary responsibility for ensuring drug quality and safety, this Announcement is hereby issued in accordance with the *Drug Administration Law of the People’s Republic of China* and the *Measures for Supervision and Administration of Drug Manufacturing*, regarding matters related to strengthening the supervision and administration of entrusted drug manufacturing.

I. Strengthening the responsibilities of entrusted manufacturers

(1) Entrusted manufacturers shall establish and improve a quality management system and ensure its continuous and effective operation. They shall strictly comply with Good Manufacturing Practice for Pharmaceutical Products (hereinafter referred to as “GMP”), and, on the basis of sufficient technical transfer studies, organize production in strict accordance with national drug standards and the formulation and manufacturing processes approved by the drug regulatory authority. They shall effectively fulfil the obligations and responsibilities stipulated in the entrusted manufacturing agreement and quality agreement.

(2) Entrusted manufacturers shall possess organizational structures, personnel, premises, facilities, and equipment compatible with the entrusted products, and shall have corresponding quality assurance and risk management capabilities to ensure that the production process continuously complies with legal and regulatory requirements.

(3) Entrusted manufacturers shall establish an evaluation mechanism for holders and entrusted products. Prior to accepting an entrustment, entrusted manufacturers shall conduct a comprehensive evaluation of the holder and the products intended for entrusted production. The evaluation shall focus on, inter alia, the qualification of the holder, its quality management capability, risk factors of the product to be entrusted, feasibility of technical transfer, and

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feasibility of shared-line production. Only when the evaluation is deemed satisfactory may the entrusted manufacturing agreement and quality agreement be signed. Where entrusted manufacturing occurs between enterprises within the same group operating under a unified quality management system, the evaluation requirements relating to holder qualifications and quality management capabilities may be simplified.

Entrusted manufacturers shall prioritize cooperation with holders that possess independent R&D management capabilities and have mastered key process technologies of the entrusted products. Holders shall actively cooperate with the comprehensive evaluation conducted by entrusted manufacturers and provide truthful and valid materials for such evaluation.

(4) Both parties shall strengthen risk identification, communication, analysis, assessment, and mitigation during the technical transfer process, provide proper technical training to relevant personnel, and conduct technical transfer in accordance with applicable laws, regulations, and technical guidelines, ensuring that technical transfer is sufficiently substantiated and that product quality remains consistent before and after transfer.

During the technical transfer process, if either party identifies issues in software or hardware conditions, production management, or quality management may prevent successful technical transfer, or may give rise to risks in drug manufacturing quality, they shall immediately communicate and adopt measures to control such risks. Where risks cannot be effectively controlled, cooperation shall be discontinued.

Where a third party is engaged in product R&D, the holder shall coordinate the R&D third party and the entrusted manufacturer to strengthen cooperation and jointly complete the technical transfer process.

Entrusted manufacturers shall perform the following duties during the technical transfer process:

1-Assign a responsible person to interface with the technical transfer process, establish a technical transfer working group, and clearly define the duties and responsibilities of the person in charge and members of the working group;


2-Establish and improve a technical transfer management system, review the feasibility of technical transfer plans formulated by all parties involved in the transfer, and implement the requirements of such plans;

3-Conduct qualification or validation activities for facilities and equipment, cleaning methods, analytical methods, and manufacturing processes in accordance with applicable laws and regulations, as well as perform co-line production risk assessments and other related work;

4-Cooperate with the marketing authorization holder in consolidating and analyzing technical transfer data and records, review technical transfer reports, and ensure that all records and data generated during the technical transfer process are true, accurate, complete, and traceable;

(5) Based on the results of qualification or validation activities and co-line production risk assessments, and in combination with the holder's technical transfer documentation and





outcomes, establish technical documents such as manufacturing process procedures and blank batch records, which shall be reviewed and approved by the holder.

Entrusted manufacturers shall establish relevant risk prevention and control systems and cooperate with holders in conducting quality management activities such as risk assessment, validation, communication, and review, as well as the implementation of associated risk control measures. During the entrusted manufacturing of marketed products, entrusted manufacturers shall, based on product type, process characteristics, and production status, cooperate with holders in conducting quarterly risk assessment analyses and annual product quality reviews.

In the event of deviations, such deviations shall be promptly recorded and addressed, and the holder shall be notified to ensure closure of the risk. Where quality or compliance risks are identified, effective risk control measures shall be taken jointly with the holder. Where significant quality or compliance risks exist, production shall be suspended immediately. Entrusted manufacturers shall establish relevant systems to cooperate with holders in pharmacovigilance activities.


For entrusted manufacturing of high-risk products such as sterile drugs, the holder shall dispatch personnel to conduct on-site inspections at least once per year to supervise validation activities such as sterilization process validation and aseptic process simulation tests. Entrusted manufacturers shall provide access to relevant facilities and areas, supply relevant records, and actively cooperate with the holder in carrying out such activities.

(6) Both parties shall ensure effective alignment of quality management systems and strengthen the management of drug manufacturing and testing records and data. Entrusted manufacturers shall designate a responsible person for coordination with the holder's quality management system and clearly define their responsibilities. The quality agreement shall specify that the holder has the right to access management systems, operating procedures, and documentation related to entrusted manufacturing activities, as well as to inspect relevant facilities, to ensure that entrusted manufacturing complies with applicable laws, technical standards, and the holder's quality requirements.

(7) Entrusted manufacturers and holders shall establish a quality information communication procedure and, in accordance with risk management principles, develop a communication information list (including at minimum deviations, changes, out-of-specification/out-of-trend test results, qualification and validation activities, retention samples and stability studies, pharmacovigilance activities, regulatory inspection outcomes, and adverse credit records). They shall define communication personnel and responsibilities, communication methods, and timelines to ensure smooth, timely, and effective communication.

(8) Entrusted manufacturers shall strengthen co-line production risk management in accordance with relevant provisions such as the *Guidelines for Quality Risk Management of Co-line Drug Production*. Where changes occur in co-line production conditions (such as addition of commercially manufactured products, addition of non-commercial products, formulation or manufacturing process changes, equipment or facility changes, or other significant changes),





entrusted manufacturers shall produce a clear and definitive risk assessment conclusion for co-line production, implement effective risk control measures based on such conclusions, and promptly notify all holders of products produced on the same line.

Where business confidential information is involved, it may be omitted from the notification. Entrusted manufacturers shall carefully evaluate feedback from holders, adopt corresponding measures, and reach agreement with holders. Where risks or potential hazards are identified, corrective and preventive actions approved by the holder shall be implemented.

Entrusted manufacturers shall, taking into account designed production capacity, co-line production risk assessments, cleaning validation, production management, and materials and finished product management, reasonably determine the number of entrusted products and production schedules to ensure that production capacity remains within a reasonable range at all times.

(9) Entrusted manufacturers shall establish a change control system in accordance with relevant provisions on drug change management and the requirements of GMP for pharmaceutical products, and shall conduct thorough change studies and control measures.

No changes involving entrusted products may be implemented without the approval of the marketing authorization holder. Entrusted manufacturers shall cooperate with holders in conducting studies related to changes, determining the category of such changes, and assisting holders in completing approval, filing, or reporting procedures in accordance with the law. Where the parties fail to reach agreement on the classification of a change, the change shall be managed at the higher risk level.

Where either the entrusted manufacturer or the holder determines, based on assessment, that an implemented change presents quality risks, corresponding measures shall be taken in a timely manner to eliminate such risks.

(10) Where a single entrusted manufacturer is engaged by multiple holders to manufacture drugs with the same generic name, or where the entrusted manufacturer itself holds products with the same generic name, it shall strictly implement full-process production and documentation management. Separate process specifications, quality standards, and testing methods shall be established for each product formulation, and production processes shall be strictly segregated and independently managed.

Material management shall also be strengthened, and the management of critical materials, intermediates, and finished dosage forms shall be kept strictly separate to avoid mix-ups and to ensure traceability.

Where a holder entrusts multiple manufacturers to produce the same drug, it shall ensure that all entrusted manufacturers produce in accordance with the approved manufacturing process. Where differences exist in production conditions based on the approved process, entrusted manufacturers shall cooperate with the holder in conducting comparative analysis, assess any differences for risk, and establish corresponding risk mitigation measures. The holder shall conduct regular comparative quality studies to ensure product quality consistency.



(11) Holders and entrusted manufacturers shall strengthen retention sample management and stability studies. Where the holder deems it necessary based on assessment, both parties shall retain samples of relevant materials or conduct retention sampling and ongoing stability studies for relevant finished products, to ensure compliance with drug traceability and investigational requirements.

For batches associated with major deviations during production, as well as the first three batches produced after approval of major changes, both parties shall conduct retention sampling and ongoing stability studies for the relevant finished products. Retention and stability studies conducted by the holder may be performed in-house or entrusted to qualified third-party institutions. Where third-party institutions are engaged, oversight of their activities shall be strengthened.

Where drug manufacturing is conducted between enterprises within the same group under a unified quality management system, or where the entrusted manufacturer adopts an information system to record full-process production and testing data and can exchange electronic data with the holder, retention and ongoing stability studies may be conducted by either the holder or the entrusted manufacturer.

(12) Entrusted manufacturers shall establish standard operating procedures for drug factory release in accordance with laws, regulations, and GMP requirements, and clearly define release standards and conditions. Drugs that meet the established standards, conditions, and legal requirements may only be released from the factory after being signed off by the qualified person.

At the time of factory release, entrusted manufacturers shall submit relevant batch production records, batch testing records, deviation investigation records, and other related documentation and data to the holder.

At the time of marketing release, the holder shall strictly review drug quality test results, key production records, and deviation control status, and where necessary, review batch production records, batch testing records, deviation investigation records, and other related documentation and data associated with entrusted production.

(13) Entrusted manufacturers shall actively cooperate with holders in conducting periodic on-site audits and in regulatory inspections or extended inspections conducted by provincial drug regulatory authorities at the holder's location. They shall not conceal true information or provide false materials, and shall promptly rectify any issues identified during audits or inspections. After completion of on-site audits of entrusted manufacturers, the holder shall promptly prepare an on-site audit report.

(14) Entrusted manufacturers shall retain full-process production and testing data and records in accordance with GMP requirements, ensuring that all data are authentic, accurate, complete, and traceable.

Holders and entrusted manufacturers are encouraged to establish an information management system covering the entire process of material management, drug production, and testing, and



to use digital systems to facilitate transmission, review, and archiving of documents and data throughout the production and testing process.

Where entrusted manufacturers use electronic systems to record full-process production and testing data and are capable of electronic data exchange with the holder, the holder may, during periodic review activities, replace part of on-site audits with off-site (remote) audits.

(15) Holders and entrusted manufacturers shall, in light of product characteristics and the actual circumstances of entrusted manufacturing, refine quality management measures in accordance with laws and regulations, and promptly update entrusted manufacturing agreements and quality agreements to ensure that their contents remain consistent with the management systems, documented procedures, and other relevant requirements of both parties. They shall strictly perform the obligations and responsibilities stipulated in such agreements.

II. Strengthening the Supervision and Administration of Entrusted Manufacturing

(16) Where an entrusted manufacturer intends to apply for the issuance of a Drug Manufacturing License for entrusted manufacturing (hereinafter referred to as a “Category C License”) or for a change to the licensed items of a Category C License, provincial drug regulatory authorities shall conduct strict review in accordance with the *Measures for the Supervision and Administration of Drug Manufacturing* (Order No. 28 of the State Administration for Market Regulation), the *Announcement of the National Medical Products Administration on Matters Concerning the Implementation of the Revised Measures for the Supervision and Administration of Drug Manufacturing* (No. 47 of 2020), the *Announcement of the National Medical Products Administration on Strengthening the Supervision and Administration of Entrusted Manufacturing by Marketing Authorization Holders* (No. 132 of 2023), and the requirements of this Announcement. A Category C License shall be issued or relevant changes approved only where all requirements are met.

(17) Where entrusted manufacturing of sterile drugs is intended, in principle, at least one of the holder or the entrusted manufacturer shall have not less than three years of experience in the commercial-scale production of sterile drugs of the same dosage form.

Under any of the following circumstances, entrusted manufacturing of sterile drugs may also be carried out where either the holder or the entrusted manufacturer has at least three years of experience in the research and development or manufacturing of sterile drugs of the same dosage form:

1-The drug falls within the categories of innovative drugs, improved new drugs, nationally designated shortage drugs, clinically essential drugs in short supply, urgently needed clinical drugs, drugs urgently required for responding to public health emergencies, drugs for the treatment of rare diseases, or cases where overseas-manufactured drugs already marketed domestically are transferred to domestic production;



2-Entrusted manufacturing of sterile drugs conducted between enterprises within the same group operating under a unified quality management system;

3-The entrusted manufacturer adopts information-based systems to record full-process data for material management, drug production, and testing, and is capable of electronic data exchange with the holder;

4-The entrusted manufacturer has been primarily involved in the research and development or clinical trial manufacturing of the sterile drug to be entrusted.

Where entrusted manufacturing of sterile drugs is intended, the head of production, the head of quality, and the qualified person of the entrusted manufacturer shall each have at least five years of practical experience in drug production and quality management, of which at least three years shall be in sterile drug production and quality management. Where entrusted manufacturing involves traditional Chinese medicine injections or multi-component biochemical drugs, such personnel shall also have at least three years of practical experience in the production and quality management of the same type of formulation.

(18) For products that have not undergone marketing release of commercial-scale batches during the re-registration cycle, where a holder intends to entrust manufacturing, production shall first be resumed in accordance with the requirements for resumption of production of drugs that have been suspended for a long period, as set out in the *Procedures for Drug Re-registration Applications for Domestically Manufactured Drugs* issued by the National Medical Products Administration.

For nationally designated shortage drugs, clinically essential drugs in short supply, drugs that have passed consistency evaluation for generic drugs, and drugs that were previously manufactured under entrusted manufacturing arrangements prior to production suspension, holders may resume production through entrusted manufacturing.

Where relevant production lines have been idle for a prolonged period (more than three years for sterile production lines and more than five years for other types of production lines) and are intended to resume production, the drug manufacturer shall conduct qualification and validation prior to resumption and apply to the provincial drug regulatory authority at its location for a GMP compliance inspection. The product submitted for inspection may be a product held by the manufacturer or an entrusted product. Entrusted manufacturing may only be undertaken after passing such inspection.

(19) Where both the holder and the entrusted manufacturer are located within the same provincial administrative region and intend to apply for licensing matters related to entrusted manufacturing, the provincial drug regulatory authority is not required to issue an *Opinion Letter on Entrusted Drug Manufacturing*, and may process, in parallel, the relevant licensing matters for the Drug Manufacturing License for entrusted manufacturing (hereinafter referred to as a “Category B License”) and the Category C License.



Where the holder and the entrusted manufacturer are located in different provincial administrative regions and intend to apply for licensing matters related to entrusted manufacturing:

1. Where the entrusted manufacturer has not yet obtained a Drug Manufacturing License, or where it is necessary to add a new manufacturing site or expand the manufacturing scope, the entrusted manufacturer shall apply to the provincial drug regulatory authority at its location for the issuance of a Category C License or for changes to licensed items, in accordance with the *Announcement of the National Medical Products Administration on Matters Concerning the Implementation of the Revised Measures for the Supervision and Administration of Drug Manufacturing* (No. 47 of 2020) and other applicable requirements. Where the requirements are met, the provincial authority shall process the issuance or change of the Category C License in accordance with procedures and shall, based on the results of the GMP compliance inspection or licensing inspection (inspection requirements set out in Annex 1), simultaneously issue the *Opinion Letter on Entrusted Drug Manufacturing* (template set out in Annex 2).

2. Where the entrusted manufacturer already holds a Drug Manufacturing License covering the relevant manufacturing site and scope, it shall submit application materials to the provincial drug regulatory authority at its location. The authority shall strictly review the application materials and, based on the results of GMP compliance inspections or licensing inspections, issue the *Opinion Letter on Entrusted Drug Manufacturing*. Inspections shall be conducted where necessary.

After obtaining the *Opinion Letter on Entrusted Drug Manufacturing*, the holder shall, within 12 months, apply to the provincial drug regulatory authority at its location for the Category B License. The provincial authority shall strictly review the application materials submitted by the holder and conduct on-site inspections in accordance with regulations. Where the requirements are met, it shall issue the Category B License or approve the relevant changes.

After the holder has completed the licensing formalities for the Category B License, the entrusted manufacturer shall, within 60 working days, apply to the provincial drug regulatory authority at its location to record the relevant changes—such as the names of both parties, product name, and approval number—on the copy of its Drug Manufacturing License.

(20) Licensing matters related to entrusted manufacturing shall be handled in accordance with the provisions of Article 16 of the *Measures for the Supervision and Administration of Drug Manufacturing* concerning changes to manufacturing sites or manufacturing scope, and no separate validity period shall be established.

Where the Drug Manufacturing Licenses of the holder or the entrusted manufacturer expire and are renewed, the provincial drug regulatory authority at the location of the entrusted manufacturer may, upon reissuance, waive the requirement to issue a new *Opinion Letter on Entrusted Drug Manufacturing*.

Where an application for marketing authorization fails to obtain approval, where the relevant manufacturing conditions are not met, or where entrusted manufacturing activities are terminated due to contractual or other reasons, the holder and the entrusted manufacturer shall, within six months of termination, proactively apply to the provincial drug regulatory



authority at their respective locations to cancel or reduce the corresponding entrusted manufacturing scope.

(21) The provincial drug regulatory authority at the location of the contracted manufacturing enterprise shall, based on risk, conduct targeted inspections of such enterprise, with a focus on the operation of its quality management system. Where the quality management system fails to operate in a sustained and effective manner, or where suspected violations of laws or regulations exist, such authority shall promptly investigate and handle the matter in accordance with the law. Inspections of contracted manufacturing enterprises may be conducted concurrently with routine inspections, licensing inspections, and extended inspections carried out by the provincial drug regulatory authority at the location of the marketing authorization holder.

Provincial drug regulatory authorities shall, based on risk, carry out quality sampling inspections of products subject to contract manufacturing. The provincial authority at the location of the marketing authorization holder may conduct sampling and testing during the stages of production, distribution (including online drug transactions), and use, or may request the provincial authority at the location of the contracted manufacturing enterprise to conduct sampling and/or testing during the production stage.

(22) In accordance with the principle of territorial supervision, provincial drug regulatory authorities shall, during the approval process for drug contract manufacturing permits and in routine supervision, strengthen the assessment and evaluation of the performance capabilities of key personnel of both contracting parties. Based on such evaluations and inspection results, measures such as regulatory interviews, warnings, and orders for rectification within a prescribed time limit may be imposed. Where the performance capability of key personnel is found to be inadequate, further risk control measures, including suspension of production or sales, may be adopted where necessary.

(23) Provincial drug regulatory authorities shall utilize platforms such as drug safety credit archives and the national drug sampling inspection information system to ensure the transmission of supervisory inspection information and quality sampling data for cross-provincial contract-manufactured products, establish a smooth coordination mechanism for joint supervision, and form an effective closed-loop regulatory system.

(24) Where a marketing authorization holder or a contracted manufacturing enterprise is found, in the process of applying for a production permit, to have provided false personnel resumes, fabricated data, records, or on-site assessment reports, such conduct shall be handled in accordance with Article 123 of the *Drug Administration Law* and other relevant provisions.

Where, during the contracted manufacturing period, a contracted manufacturing enterprise engages in the production of counterfeit or substandard drugs, fabricates production or inspection records, releases products without complying with applicable legal and regulatory requirements, fails to follow the manufacturing process provided by the marketing authorization holder, or otherwise fails to comply with Good Manufacturing Practice (GMP) requirements, it



shall bear corresponding legal liabilities. The provincial drug regulatory authority at its location shall handle such violations in accordance with Articles 116, 117, 124, 126, and 127 of the *Drug Administration Law*.

The provincial drug regulatory authority at the location of the contracted manufacturing enterprise shall promptly notify the provincial authority at the location of the marketing authorization holder of the aforementioned violations and the actions taken.

III. Other Matters

(25) Provincial drug regulatory authorities shall strengthen policy dissemination and urge marketing authorization holders and contracted manufacturing enterprises to conduct comprehensive self-inspections in accordance with the requirements of this Announcement. Where contract manufacturing arrangements are inconsistent with the requirements herein, both parties shall communicate and formulate rectification plans. In principle, rectification shall be completed within one year from the date of issuance of this Announcement. Where certain items require more than one year, the reasons and completion timeline shall be specified.

Provincial authorities shall supervise and urge timely rectification. Where rectification is not completed within the prescribed period, contract manufacturing activities shall be suspended in accordance with the law, or the approved scope of production shall be reduced, up to and including revocation of the Drug Manufacturing License.


(26) Support is provided for innovative drugs, modified new drugs, nationally designated shortage drugs, nationally clinically essential drugs prone to shortage, urgently needed clinical drugs, drugs required for responding to public health emergencies, drugs for rare diseases, and cases where drugs already marketed overseas are transferred to domestic production. Such products are encouraged to expand capacity or accelerate market entry through contract manufacturing.

(27) Newly established contracted manufacturing enterprises, or newly added production lines for contracted products involving drugs selected through national centralized procurement or high-risk drugs, are encouraged to implement manufacturing execution systems (MES), laboratory information management systems (LIMS), document management systems (DMS), warehouse management systems (WMS), and other digitalized quality management systems, and to continuously improve their quality management systems.

The development of contract development and manufacturing organizations (CDMOs) with strong R&D capabilities, proven ability to bring products to market, and high levels of specialization is encouraged, and such enterprises are supported in undertaking contract manufacturing. Enterprises are also supported in accepting inspections by World Health Organization Listed Authorities (WLA).

(28) This Announcement shall come into force as of the date of its issuance. Applications for drug manufacturing permits and drug registrations that have already been accepted prior to the issuance of this Announcement shall be handled in accordance with the previous





requirements. Exceptions shall apply where otherwise stipulated by laws, regulations, rules, or the national drug regulatory authority under the State Council.

