Regulations on Inspection of Exported Drugs and Management of Export Certificates for Pharmaceutical Manufacturers [1]

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Chapter I: General Provisions

Article 1

In order to support the export trade of pharmaceuticals and to strengthen the supervision of inspections and the issuance of export certificates for pharmaceutical products manufactured for export, these Provisions are hereby formulated.

Article 2

For the purposes of these Provisions, *export pharmaceuticals* refer to products manufactured within the territory of the People's Republic of China by enterprises holding a valid *Pharmaceutical Manufacturing Licence* (hereinafter referred to as "export pharmaceutical manufacturing enterprises"), which are exported to other countries or regions and, in the importing country or region, are regulated as pharmaceutical products and placed on the market. This includes products already marketed in China as well as products not marketed domestically.

Article 3

The National Medical Products Administration (NMPA) shall provide guidance to provincial-level medical products administrations regarding the inspection of pharmaceuticals intended for export and the issuance of export certificates.

Provincial-level medical products administrations shall guide export pharmaceutical manufacturing enterprises within their respective jurisdictions in establishing export pharmaceutical dossiers and shall conduct the required inspections. They shall record relevant

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

export pharmaceutical information in the *Pharmaceutical Manufacturing Licence* and, upon the enterprise's application, issue the corresponding export certificates.

Chapter II: Basic Requirements

Article 4

Export pharmaceutical manufacturers shall possess production conditions that are compatible with the export pharmaceutical products, and shall strictly manufacture export pharmaceuticals in accordance with Good Manufacturing Practice (GMP) at the production address, within the production scope, and in the production workshops and production lines specified in the *Drug Manufacturing Certificate*. The formulation, manufacturing process, quality standards, labels, package inserts and other related documentation of export pharmaceuticals shall comply with the requirements of the importing country (or region).

Where an export pharmaceutical manufacturer also produces chemical products or other non-pharmaceutical products, such products must not be exported under the name of pharmaceuticals, nor may the *Drug Manufacturing Certificate* or any other documents issued by the drug regulatory authorities be used in the trade of such non-pharmaceutical products.

Article 5

The production scope, production workshops, and production lines related to export pharmaceuticals of an export pharmaceutical manufacturer shall pass GMP compliance inspection, and the production address, production scope, production workshops, and production lines of export pharmaceuticals shall be indicated in the *Drug Manufacturing Certificate*.

For pharmaceuticals that have not been marketed within China but have obtained prequalification or authorization for production from an international organization with which China has relevant agreements, the provincial drug regulatory authority may, upon the manufacturer's application, indicate the production address, production scope, production workshops, and production lines of the relevant pharmaceuticals in the *Drug Manufacturing Certificate*, and exempt them from the corresponding on-site inspections.

Article 6

Where different pharmaceutical products are manufactured in the production workshops or on the production lines used for export pharmaceuticals, or where the same pharmaceutical product is manufactured using different processes or quality standards, the manufacturer shall strengthen production management, conduct a co-line production risk assessment, prepare a co-line production risk assessment report, and incorporate such report into the export pharmaceutical dossier.

Article 7

Export pharmaceuticals shall be fully packaged and bear labels and package inserts at the time of batch release.

Where export pharmaceuticals are supplied in bulk packaging (to be repackaged into the smallest marketing unit after export), such bulk-packaged preparations shall bear labels at the time of batch release.

The contents of the labels and package inserts shall specify the name and production address of the export pharmaceutical manufacturer and shall be approved by the drug regulatory authority of the importing country (or region).

Where the labels or package inserts approved by the drug regulatory authority of the importing country (or region) do not include the manufacturer's information, or where, pursuant to the laws and regulations of the importing country (or region), such labels or package inserts do not require approval by its drug regulatory authority, the manufacturer shall ensure that the labels and package inserts comply with the requirements of the importing country (or region), and shall provide a written explanation, which shall be incorporated into the export pharmaceutical dossier.

Export pharmaceutical manufacturers shall not manufacture or release products without labels or products whose label information is inconsistent with the actual product.

Article 8

Export pharmaceuticals shall comply with the storage and transportation requirements of the importing country (or region). The storage and transportation activities conducted within the territory of China may be carried out with reference to the relevant requirements of the Good Supply Practice (GSP) for pharmaceuticals.

Article 9

The export pharmaceutical manufacturer shall bear the primary responsibility for the quality management of the storage and transportation of export pharmaceuticals; where production is entrusted, the entrusting party shall bear such primary responsibility. The export pharmaceutical manufacturer or the entrusting party may undertake the storage and transportation of export pharmaceuticals on its own, or may entrust a pharmaceutical wholesale enterprise or other entity with the requisite qualifications or capability to conduct storage and transportation activities for export pharmaceuticals.

The export pharmaceutical manufacturer or the entrusting party shall provide a letter of commitment agreeing to accept extended inspections of the storage and transportation process by the drug regulatory authority. Where storage and transportation are entrusted to another entity, the manufacturer or entrusting party shall ensure—through the execution of a storage and transportation agreement or other contractual arrangements—that the entrusted entity accepts audits and extended inspections by the drug regulatory authority. The letter of commitment, storage and transportation agreement, and related documents shall be incorporated into the export pharmaceutical dossier.

Chapter III: Acceptance of Contract Manufacturing for Export Pharmaceuticals

Article 10

Where a pharmaceutical manufacturing enterprise accepts a commission to produce medicinal products for export, the commissioning party shall be the holder or applicant of the marketing authorization (including filing or equivalent procedures, hereinafter the same) for the said medicinal product in the importing country (or region), or shall meet one of the following conditions:

1-Where the exported medicinal product has already been marketed within China or a marketing authorization application has been submitted in China, the commissioning party may be the marketing authorization holder or applicant for that product within China.

2-Where the exported medicinal product is an innovative drug, an originator drug, or an improved-type drug, the commissioning party may be the holder or applicant of the marketing authorization for that medicinal product in the importing country (or region), or an agent duly designated by such holder or applicant.

The pharmaceutical manufacturing enterprise shall enter into a commissioned manufacturing agreement and a quality agreement directly with the commissioning party, and shall specify that the medicinal product for export must comply with all applicable laws and regulations of the importing country (or region).

Article 11

Pharmaceutical manufacturing enterprises producing medicinal products for export shall rigorously examine the authenticity and legality of all documents provided by the commissioning party, and shall prudently assess the legal risks associated with accepting a commissioned manufacturing arrangement for exported medicinal products.

Where there is doubt regarding the authenticity or legality of any marketing authorization documents or similar materials issued overseas, the manufacturing enterprise shall require the commissioning party to obtain notarization in the country (or region) where such documents were issued, as well as certification or supplementary documentation possessing equivalent certification validity.

Article 12

Pharmaceutical manufacturing enterprises that accept commissioned production of medicinal products for export shall strictly carry out production in accordance with Good Manufacturing Practice (GMP) requirements, the commissioned manufacturing agreement, and the quality agreement.

They shall not subcontract or re-delegate the commissioned manufacturing of such medicinal products to any third party.

Chapter IV: Dossier for Export Pharmaceuticals

Article 13

Export pharmaceutical manufacturers shall establish dossiers for export pharmaceuticals. For pharmaceutical preparations, the dossier for export pharmaceuticals shall be established on a per-specification (unit dosage) basis; for active pharmaceutical ingredients and traditional Chinese medicine formula granules, the dossier shall be established on a per-variety basis.

Where the export pharmaceutical product has already been marketed within China or a marketing authorization application has been submitted in China, the marketing authorization holder or the applicant within China shall be responsible for establishing the dossier for the export pharmaceutical on the basis of the approval number or the application acceptance number. In such cases, the contract manufacturer for the export pharmaceutical is not required to establish a dossier for that product.

Where information required for the dossier for export pharmaceuticals needs to be provided by relevant enterprises, such enterprises shall cooperate with the dossier creator and provide the required information truthfully.

Article 14

The dossier for export pharmaceuticals shall include the following information or materials. Where any material is in a language other than Chinese or English, a Chinese translation bearing the official seal of the entity establishing the dossier shall be provided concurrently:

1-The importing country or region of the export pharmaceutical.

2-The nonproprietary name, trade name, dosage form, specification (unit dosage), packaging specification, and other relevant information of the export pharmaceutical in the importing country or region.

3-The marketing authorization document obtained by the export pharmaceutical in the importing country or region. The marketing authorization document shall include the name and production address of the export pharmaceutical manufacturer. Where the importing country or region does not administer pharmaceuticals through a marketing authorization document, or where the marketing authorization document does not include manufacturer information, an explanatory statement shall be provided in accordance with the laws and regulations of the importing country or region.

4-The quality standards of the export pharmaceutical that meet the requirements of the importing country or region.

5-The name and production address of the manufacturer, as well as the production workshops and production lines used for the export pharmaceutical.

6-The co-line production risk assessment report related to the export pharmaceutical, prepared in accordance with Article 6 of these Provisions.

7-The label and package insert approved in the importing country or region. Where the labels or package inserts approved by the drug regulatory authority of the importing country or region do not include the manufacturer's information, or where, pursuant to the laws and regulations of the importing country or region, such labels or package inserts do not require approval by the drug regulatory authority, an explanatory statement shall be provided in accordance with Article 7 of these Provisions.

8-The letter of commitment, storage and transportation agreements, and other documents that comply with Article 9 of these Provisions.

9-Where the export pharmaceutical is manufactured under a contract manufacturing arrangement, the contract manufacturing agreement, the quality agreement, and the business licenses of both the entrusting party and the entrusted manufacturer shall be submitted. Where the entrusting party is located outside China, commercial registration documents issued by the country or region of the entrusting party shall also be submitted.

10-Information on the annual production and sales volume of the export pharmaceutical. The information for the preceding calendar year shall be submitted before April 30 of each year. For pharmaceuticals already marketed within China, only the production and sales volumes for export shall be reported.

11-Where the export pharmaceutical manufacturer has been inspected by an international organization or by a foreign drug regulatory authority, the dates, scope, and conclusions of all inspections conducted since January 1, 2024 shall be provided.

12-The export certificate obtained for the export pharmaceutical.

13-The compliance declaration for the export pharmaceutical (template provided in Annex 1).

14-The formulation and manufacturing process of the export pharmaceutical that comply with the requirements of the importing country or region.

15-The batch records, pre-customs-clearance storage and transportation records, and customs declaration documents for the export pharmaceutical.

Article 15

The entity establishing the export drug dossier shall submit Items (1) through (13) of Article 14 into the information system constructed by the drug regulatory authority. If any materials previously submitted to the information system require correction, the entity may submit the corrected materials along with relevant explanations to the information system.

Items (14) and (15) of Article 14 shall not be included in the information system constructed by the drug regulatory authority and shall be properly retained by the entity establishing the export drug dossier. Such materials shall be truthfully provided during inspections conducted by the drug regulatory authority.

In particular: Prescriptions and production processes shall be retained long-term. If the dossier-establishing entity is an export drug manufacturer producing under commission, retention shall be in accordance with the period stipulated in the commission and quality agreements. Batch records, storage and transportation records prior to customs declaration, and customs declaration documents shall be retained for at least one year after the drug's expiration date. Active pharmaceutical ingredients (APIs) subject to re-inspection periods shall be retained until all batches have been shipped for that production batch, and for no less than three years thereafter.

Article 16

The entity establishing the export drug dossier shall complete the relevant export drug dossier within 30 working days after commencing new export drug business. For entities that already have export drug business at the time of the implementation of these provisions, the export drug dossier shall be completed within 30 working days after the provisions come into effect.

The export drug dossier shall continuously reflect the actual production and sales status of the enterprise's export drugs. If updates are necessary, the updated materials shall be incorporated into the export drug dossier within 30 working days after the relevant events occur.

Article 17

If the export drug dossier contains commercial information that must be protected according to law, the entity establishing the export drug dossier or the holder of the relevant information may apply protective measures such as masking or hiding the information. However, it shall be ensured that the information included in the dossier remains sufficient to meet the requirements of inspections conducted by the drug regulatory authority.

Chapter V: Export Certificates

Section 1 – General Requirements for Export Certificates

Article 18

The export certificates referred to in these provisions include the "Certificate of Pharmaceutical Export Sales" and the "Certificate for Export of EU Active Pharmaceutical Ingredients."

Export certificates do not apply to drugs whose export is prohibited by the relevant departments of the State Council.

Article 19

An export drug manufacturer shall apply to the provincial-level drug regulatory authority in its place of registration for the issuance of an export certificate.

If the export drug has already been marketed in China or has a marketing authorization application submitted in China, the marketing authorization holder or applicant of the drug in China may apply to the provincial-level drug regulatory authority in its place of registration for the issuance of an export certificate.

Article 20

During the process of issuing an export certificate, the provincial-level drug regulatory authority shall review the application in conjunction with prior inspections of compliance with Good Manufacturing Practices (GMP).

If the review of the submitted materials indicates compliance with GMP requirements, an on-site inspection may be waived. If the review of the submitted materials does not sufficiently demonstrate compliance with GMP requirements, a GMP compliance inspection shall be conducted.

If the inspection concludes that the requirements are met, the export certificate shall be issued. If the requirements are not met, the export certificate shall not be issued, and the matter shall be handled in accordance with applicable laws and regulations.

Article 21

The validity period of an export certificate is three years and shall, in principle, not exceed the validity period of all submitted application materials.

If the remaining validity of the application materials is less than three years, the applicant may provide a written commitment to apply for an extension before the expiration of the relevant materials; in such cases, the validity of the export certificate shall not be limited by the current validity of the application materials.

After obtaining the export certificate, if the applicant fails to fulfill the above commitment, the provisions of Article 40 of these Regulations shall apply. If the materials' extension is applied for but not approved, the holder of the export certificate shall void the export certificate before the expiration of the application materials' validity.

Article 22

The provincial-level drug regulatory authority shall submit information on export certificates to the National Medical Products Administration (NMPA) through the information system. The NMPA shall publicly disclose the information on the government website, marking export certificates that have been voided or have expired as invalid.

Article 23

Provincial-level drug regulatory authorities may formulate their own guidelines for the issuance of export certificates in accordance with these provisions, specifying the work procedures, processing timelines, and related requirements. The maximum processing period shall not exceed 20 working days. The time required for technical review and evaluation, on-site inspections, and enterprise corrective actions shall not be counted within the processing period.

Article 24

For intermediate products of pharmaceutical preparations produced by drug manufacturing enterprises that are used for producing pharmaceutical preparations in the importing country (region), if the importing country (region) requires an export certificate for the intermediate products, the provincial-level drug regulatory authority may, upon the enterprise's application, issue an export certificate in accordance with the requirements of these provisions, treating the product as a type not yet marketed in China.

Article 25

Electronic export certificates shall have the same legal effect as paper certificates.

Section 2 – Certificate of Pharmaceutical Export Sales

Article 26

The "Certificate of Pharmaceutical Export Sales" applies to export drugs produced by export drug manufacturers in accordance with Good Manufacturing Practices (GMP). The certificate is applicable for importing countries (regions) that are members of the World Health Organization (WHO) International Certificate Scheme on Pharmaceutical Trade or other countries (regions) that require such a certificate.

Article 27

The "Certificate of Pharmaceutical Export Sales" shall be issued in accordance with the template attached to these provisions (see Appendix 2).

Export drugs that have been marketed in China and simultaneously meet both Chinese and importing country (region) quality standards may apply for the "Certificate of Pharmaceutical Export Sales" as drugs already marketed in China.

If the drugs do not meet Chinese quality standards, or if the formulation or production process differs from that of the drugs marketed in China, the application for the "Certificate of Pharmaceutical Export Sales" shall be made as drugs not yet marketed in China.

For drugs not marketed in China, if there are multiple specifications (unit doses), formulations, production processes, or quality standards, a separate application for the "Certificate of Pharmaceutical Export Sales" shall be submitted for each different specification (unit dose), formulation, production process, or quality standard.

Article 28

The application materials for the Certificate of “Pharmaceutical Export Sales” are as follows:

1-The "Application Form for the Certificate of Pharmaceutical Export Sales" (template see Appendix 3).

2-For biological products already marketed in China and managed under batch release, a test report issued by the batch release institution or a "Batch Release Certificate for Biological Products" shall be submitted.

3-For pharmaceutical preparations or active pharmaceutical ingredients not approved for marketing in China, or traditional Chinese medicine formula granules not yet completed for marketing recordation, the production process (brief description) and quality standards shall be submitted.

4-For products involving contract manufacturing, the contract manufacturing agreement and quality agreement for the relevant product shall be submitted (if agreements have not yet been signed, a letter of intent for contract manufacturing may be submitted). When the application is submitted by the marketing authorization holder or applicant in China, a statement regarding the audit of the contract manufacturer shall also be submitted. When the application is submitted by the contract manufacturer, a "Declaration for Handling the Certificate of Pharmaceutical Export Sales on Behalf of the Entrusting Party" (template see Appendix 4) shall also be submitted.

5-Export drugs pre-certified or authorized for production by international organizations that have relevant agreements with China may submit supporting documents.

6-If the remaining validity of the application materials is less than three years and the applicant intends to apply for an extension before expiration, a written commitment in accordance with the requirements of Article 21 of these provisions shall be submitted.

7-The applicant's "Business License." For export drugs involving contract manufacturing, the business licenses of both the entrusting and contract manufacturing enterprises shall be submitted; if the entrusting party is located abroad, a commercial registration certificate or equivalent from the country (region) of the entrusting party shall be submitted.

8-The "Pharmaceutical Production License" of the export drug manufacturer, both original and copy. The license shall indicate the production address, production scope, production workshops, and production lines relevant to the application for the export certificate. For export drugs involving contract manufacturing where the entrusting party holds a "Pharmaceutical Production License," the original and copy of the entrusting party's license shall also be inspected. The license of the entrusting party shall indicate the production scope and contract manufacturing situation for the product subject to the export certificate application.

9-Information on the most recent GMP compliance inspection conducted by the Chinese drug regulatory authority for the export drug product (or its dosage form, production workshop, or production line). For situations meeting the exemption from on-site inspection under Article 29, this item may be exempted from review.

10-Approval information for pharmaceutical preparations or active pharmaceutical ingredients already approved for marketing in China, or recordation information for traditional Chinese medicine formula granules whose marketing recordation has been completed.

Among these: Item 1 shall be completed in the information system established by the drug regulatory authority and electronically submitted to the provincial-level drug regulatory authority where the applicant is located. Items 2 through 7 shall be submitted by the applicant as applicable (upload electronic scans; if the materials are in a foreign language, a Chinese translation stamped with the applicant's official seal shall also be provided). Items 8 through 10 shall be accessed and reviewed by the provincial-level drug regulatory authority using supervisory and regulatory information.

Article 29

For pharmaceuticals that have obtained prequalification or authorized manufacturing status from an international organization with which China has a relevant agreement, the provincial-level drug regulatory authority may, upon the enterprise's application, waive the on-site inspection during the processing of the Certificate of Pharmaceutical Product for Export. After the certificate is issued, the provincial-level drug regulatory authority shall conduct subsequent inspections in accordance with the relevant inspection cycle.

Article 30

The numbering format for the Chinese version of the Certificate of Pharmaceutical Product for Export is: the provincial abbreviation + "XXXXXXXX No." In this format, digits 1 to 4 represent

the year of issuance, and digits 5 to 8 represent the serial number. Example: “Jing 20260001 No.”

Section 3- Certification for the Export of Active Pharmaceutical Ingredients (APIs) to the EU

Article 31

The "Certification for the Export of Active Pharmaceutical Ingredients to the European Union" (hereinafter referred to as the “EU API Export Certificate”) shall apply to APIs produced by pharmaceutical manufacturing enterprises in accordance with Good Manufacturing Practice (GMP) and intended for export.

Article 32

The EU API Export Certificate shall be issued in accordance with the template appended to these Provisions (see Appendix 5).

Article 33

The application materials for the EU API Export Certificate shall include the following:

1-The "Application Form for the EU API Export Certificate" (template provided in Appendix 6).

2-For APIs not approved for marketing within the territory of China—including products with production processes or quality standards differing from APIs approved for marketing domestically—the following must be submitted: the API production process, API quality standards, and self-inspection reports of three batches of samples.

3-The sales contract concerning the API concluded with the overseas purchasing enterprise.

4-For APIs intended for export that have passed the Good Manufacturing Practice (GMP) conformity inspection by the World Health Organization or the European Medicines Regulatory Authority, the relevant certification materials may be submitted.

5-If the remaining validity of the application materials is less than three years, but a renewal is intended before the expiration date, a written commitment in accordance with the requirements of Article 21 of these Provisions shall be submitted.

6-The business license of the pharmaceutical manufacturing enterprise.

7-The original and duplicate copies of the pharmaceutical manufacturing license of the pharmaceutical manufacturing enterprise. The license must indicate the production address, production scope, production workshop, and production line of the API for which the export certificate is being applied.

8-Information regarding the most recent GMP conformity inspection of the API manufacturing enterprise conducted by the domestic drug regulatory authority in China (inspection may be waived if the conditions set forth in Article 34 for exemption from on-site inspection are met).

9-Approval information for APIs already approved for marketing within China.

Among these:

Item (1) shall be filled in through the information system established by the drug regulatory authority and electronically submitted to the provincial-level drug regulatory authority where the applicant is located; Items (2) through (6) shall be submitted by the applicant as appropriate (uploading scanned electronic copies; if the materials are in a foreign language, a Chinese translation stamped with the applicant's official seal shall also be provided); Items (7) through (9) shall be reviewed and verified by the provincial-level drug regulatory authority by retrieving relevant regulatory information.

Article 34

If an enterprise has passed the Good Manufacturing Practice (GMP) conformity inspection conducted by the World Health Organization or the European Medicines Regulatory Authority, the provincial-level drug regulatory authority may waive on-site inspection during the issuance of the relevant API "Certification for Export to the European Union." However, the issuing authority must indicate in the certificate the institution that conducted the inspection. After issuing the certificate, the provincial-level drug regulatory authority shall carry out follow-up inspections in accordance with the relevant inspection cycle.

Article 35

The numbering format for the "Certification for Export of APIs to the European Union" shall be: a two-letter provincial code + two-digit year + four-digit sequential number. Example: "BJ260001."

Chapter VI: Supervision, Inspection and Risk Control

Article 36

Provincial-level drug regulatory authorities shall include export pharmaceutical manufacturing activities within the scope of supervision and inspection, and incorporate export pharmaceutical manufacturers into the annual inspection plan, establishing inspection frequencies in accordance with relevant regulations. For dosage forms of products for which export certificates have already been issued, periodic inspections shall be conducted in accordance with the inspection cycle specified in the certificate. In accordance with risk management principles, such inspections may be conducted independently or in conjunction with other types of inspections.

Article 37

Supervision and inspection shall focus on compliance with Good Manufacturing Practice (GMP), product quality risks, the completeness and standardization of export drug documentation, and whether production is organized in accordance with the prescriptions, manufacturing processes, quality standards, labels, and instructions required by the importing country (or region). Where necessary, quality testing of export drugs may be conducted; the authenticity of export drug documentation and application materials for export certificates may be verified; and extended inspections of pre-export distribution channels, storage, and transportation conditions may be carried out.

Article 38

If an export pharmaceutical manufacturer is inspected by the drug regulatory authority of the importing country (or region) and the conclusion is non-compliance, the manufacturer shall report to the provincial-level drug regulatory authority within five working days of receiving the inspection conclusion. The provincial-level drug regulatory authority shall organize an evaluation, pay attention to risks related to products already marketed in China, and, where necessary, conduct on-site inspections.

Article 39

If the provincial-level drug regulatory authority identifies that an export pharmaceutical manufacturer or other relevant entity has failed to comply with GMP requirements, it shall take risk control measures regarding the export drugs, including suspension of production or sales, and invalidate the corresponding export certificates. Investigations and actions shall be conducted in accordance with applicable laws and regulations. In cases involving cross-provincial contract manufacturing, the relevant provincial drug regulatory authorities shall cooperate to ensure effective risk control and proper investigation and handling.

Article 40

Materials in export drug files, application materials for export certificates, and other related documents shall be true and accurate. If any false materials or other deceptive acts are provided, once discovered by the provincial-level drug regulatory authority, the relevant export certificates already issued shall be invalidated, and the applicant shall be prohibited from applying for export certificates for a period of three years. Any quality risks potentially arising from false information shall be evaluated, and, if necessary, risk control measures such as suspension of production or sales shall be implemented.

Article 41

Pursuant to Articles 21, 39, and 40 of these Provisions, where the provincial-level drug regulatory authority invalidates an export certificate or implements risk control measures such as suspension of production or sales for the relevant products, the enterprise shall promptly report to the drug regulatory authority of the importing country (or region). If it is found that already exported drugs pose serious quality risks or may endanger users, the provincial-level drug regulatory authority shall also report to the National Medical Products Administration.

If a pharmaceutical manufacturer discovers counterfeit versions of its products in other countries (or regions), it shall promptly report to the drug regulatory authority of that country (or region) and take legal measures to protect its rights.

Chapter VII: Supplementary Provisions

Article 42

The export and contract manufacture for export of narcotic drugs, psychotropic substances, preparations containing narcotic drugs or psychotropic substances, precursor chemicals of controlled drugs in pharmaceutical form, preparations containing precursor chemicals of controlled drugs, as well as anabolic preparations and peptide hormones listed in the catalogue of stimulants, shall also comply with the relevant national regulations.

Article 43

Exported drugs procured by international organizations shall comply with the respective requirements of such organizations and shall be implemented with reference to these Provisions.

Article 44

Upon the implementation of these Provisions, the following regulations shall be repealed simultaneously: *Notice of the State Food and Drug Administration on Issuing the "Administrative Provisions for Record Filing of Contracted Drug Manufacturing by Overseas Manufacturers"* (Guo Shi Yao Jian An [2005] No. 541); *Notice of the State Food and Drug Administration on Strengthening Supervision of Contracted Drug Manufacturing by Overseas Manufacturers* (Guo Shi Yao Jian An [2011] No. 325); *Notice of the State Food and Drug Administration on Matters Related to the EU Active Pharmaceutical Ingredient Export Certificate* (Shi Yao Jian [2013] No. 10); *Notice of the National Medical Products Administration on Issuing the Administrative Provisions for Export and Sales Certificates of Drugs* (Guo Yao Jian Yao Guan [2018] No. 43).

In the event of any inconsistency between previous documents issued by the drug regulatory authorities and these Provisions, these Provisions shall prevail.

Attachments:

Attachment n.1

PEOPLE'S REPUBLIC OF CHINA

MEDICAL PRODUCTS ADMINISTRATION

Written confirmation for active substances exported

to the European Union (EU)

Confirmation no. (given by the issuing regulatory authority):

1. Name and address of site (including building number, where applicable):

2.Manufacturer's licence number(s):

REGARDING THE MANUFACTURING PLANT UNDER (1) OF THE FOLLOWING ACTIVE SUBSTANCE(S) EXPORTED TO THE EU FOR MEDICINAL PRODUCTS FOR HUMAN USE

Active substance(s)	Activity(ies)	Active substance(s) Registry Number[2]

THE ISSUING REGULATORY AUTHORITY HEREBY CONFIRMS THAT:

This manufacturing plant complies with the requirements of the Chinese Good Manufacturing Practice (= GMP of EU, WHO/ICH Q7);

The manufacturing plant is subject to regular, strict and transparent controls and to the effective enforcement of good manufacturing practice, including repeated and unannounced inspections, so as to ensure the protection of public health ,which is at least equivalent to that in the EU; and

[2]Record "none" in case where there is for export-only active substance, which is not registered.

In the event of findings relating to non-compliance, information on such findings is supplied by the exporting third country without delay to the EU.

Date of inspection of the plant under (1). Name of inspecting authority if different from the issuing regulatory authority:

This written confirmation remains valid until:

The authenticity of this written confirmation may be verified with the issuing regulatory authority.

This written confirmation is without prejudice to the responsibilities of the manufacturer to ensure the quality of the medicinal product in accordance with Chinese law and Directive 2001/83/EC.

Address of the issuing regulatory authority:

Name and function of responsible person:

E-mail, Telephone no., and Fax no.:

:

Signature	Stamp of the authority and date

Explanation regarding the documentation for exporting active pharmaceutical ingredients (APIs) to the European Union

1. Two-letter province code

Serial number	Name	Code letter	Serial number	Name	Code letters
1	Beijing	BJ	17	Hubei	HB
2	Tianjin	TJ	18	Hunan	HN
3	Hebei	HE	19	Guangdong	GD
4	Shanxi	SX	20	Guangxi	GX
5	Inner Mongolia	NM	21	Hainan	HI
6	Liaoning	LN	22	Chongqing	CQ
7	Jilin	JL	23	Sichuan	SC
8	Heilongjiang	HL	24	Guizhou	GZ
9	Shanghai	SH	25	Yunnan	YN
10	Jiangsu	JS	26	Xizang	XZ
11	Zhejiang	ZJ	27	Shaanxi	SN
12	Anhui	AH	28	Gansu	GS
13	Fujian	FJ	29	Qinghai	QH
14	Jiangxi	JX	30	Ningxia	NX
15	Shandong	SD	31	Xinjiang	XJ
16	Henan	HA	32	Xinjiang Production	BT

2. Name of the Manufacturer and Production Address (including building number)

This section shall be completed in both Chinese and English according to the actual production address.The basic format of the address in Chinese is: Province + County/City + Detailed Address + Postal Code. The basic format of the address in English is: Detailed Address + County/City + Province + Postal Code.

3. Name of the Active Pharmaceutical Ingredient (International Nonproprietary Name) and Processing Method

This section shall be completed in both Chinese and English. The name of the API in both languages shall be provided using its International Nonproprietary Name (INN). The term "processing method" refers to the manufacturing process of the active pharmaceutical ingredient. For example, it may be described as "chemical synthesis," "extraction from natural sources," "biological processes," or "finishing steps," depending on the specific circumstances.

4.Date of Inspection of the Manufacturing Site and Name of Any Inspection Authority Other Than the Issuing Department

This section shall be completed in both Chinese and English. The date shall be based on the most recent inspection of the enterprise for compliance with Good Manufacturing Practice (GMP).
The Chinese date format is: "year + month + day," for example: 2025 年 2 月 20 日. The English date format is: "day + English month + year," for example: 20 February, 2025.
If the enterprise has passed a GMP inspection conducted by the WHO, the European Directorate for the Quality of Medicines (EDQM), or drug regulatory authorities of EU member states, the provincial drug regulatory authority may waive the on-site inspection when processing the "Certificate for Export of Active Pharmaceutical Ingredients to the European Union." In such cases, the name of the GMP inspection authority shall be indicated in this section.

5.Validity Period of This Certificate

This section shall be completed in both Chinese and English. The validity period of the certificate shall comply with the relevant requirements and shall be calculated from the date of issuance.
For example: if the issuance date is 2 July 2026 and the validity period is three years, the certificate shall remain valid until 1 July 2029. The formats for Chinese and English dates are the same as described above.

6.Name and Position of the Responsible Person

This section shall be completed in both Chinese and English. The responsible person may be a relevant bureau leader of the provincial drug regulatory authority or the head of the designated department. The name and position shall be filled in according to the actual situation.

7. Signature, Official Seal of the Issuing Department, and Date

The signature shall be handwritten in Chinese by the responsible person, and the official seal of the provincial drug regulatory authority shall be affixed. The date of issuance shall be completed according to the actual date. The formats for Chinese and English dates are the same as described above.

8. Font, Size, Color, and Other Specifications

The font, size, color, line spacing, and layout of the certificate issued by each provincial drug regulatory authority shall be consistent with the prescribed format. The heading shall be set in accordance with the standardized Chinese and English names of the authority. Other content not intended for completion shall not be altered. The number of API entries on a single certificate may be adjusted as needed.

Attachment n.2

Application Form for Certificate for Export of Active Pharmaceutical Ingredients to the European Union

Data Verification Code:……. Application Form Number.

<table>
<tr><td rowspan="2">Name of the Manufacturer</td><td>Chinese:</td><td colspan="2">Unified Social Credit Code:</td><td></td></tr>
<tr><td colspan="4">English:</td></tr>
<tr><td rowspan="2">Address of the Manufacturer</td><td colspan="4">Chinese:</td></tr>
<tr><td colspan="4">English:</td></tr>
<tr><td colspan="3">Drug Production License Number:</td><td colspan="2">Expiration date:</td></tr>
<tr><td colspan="5">Scope of API Production under the Drug Production License:</td></tr>
<tr><td colspan="2">International Nonproprietary Name of the API</td><td rowspan="2">API Registration Number</td><td rowspan="2">GMP Compliance Passed (Yes/No)</td><td colspan="2">Processing Method</td></tr>
<tr><td>Chinese</td><td>English</td><td>Chinese</td><td>English</td></tr>
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Date, Name of Authority, Scope, and Result of the Most Recent Drug GMP Compliance Inspection Conducted by a Chinese Drug Regulatory Authority:					
Date, Name of Authority, Scope, and Result of the Most Recent Drug GMP Compliance Inspection Conducted by the WHO or an EU Drug Regulatory Authority:					
Name of Exporting Company:				Destination Country in the EU:	
Address of the Exporting Company:					
Name of the Importing Company:				Country:	
Reporting Contact:	Department:		Position:		
Landline Telephone:	Mobile phone number:		E-mail:		
Our company guarantees that the production process of the above-mentioned active pharmaceutical ingredients fully complies with the relevant GMP requirements of China and the European Union, and that the products meet the quality standards specified in the agreement upon inspection.					

Signature of the Responsible Person and Official Seal of the Company: Year- Month- Day

Note:

1.When completing this form online using the NMPA Export Certificate Management System for Active Pharmaceutical Ingredients to the EU, each time the application page is successfully saved, the system will automatically generate a new "Data Verification Code" to ensure that the electronic data recognized by the system is consistent with the printed version submitted by the applicant.

2.The application form number shall be filled in by the personnel of the provincial drug regulatory authority.