Provisional Regulation on the Administration of Designated Domestic Responsible Person by Overseas Drug Marketing Authorization Holders[1]

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Article 1- This regulation has been drafted in accordance with the *Law of People's Republic of China on Drug Administration*, the *Law of People's Republic of China on Vaccines Administration Law* and other relevant Law and Regulations. This regulation aims to strengthen the supervision and management control of overseas drug marketing license, to implement the main responsibility for post marketing quality of drugs and to regulate the activities for foreign drugs marketing certificate holders in designating the responsible person in China.

Article 2- The overseas holders mentioned in this regulation refers to people who have obtained the drug registration certificate issued by the China National Medical Products Administration (CNMPA). Overseas holders shall be responsible for the security, effectiveness and quality supervision of the entire marketing process (production, operation and use) of the drug for which they hold a registration certificate, in accordance with the Law. The domestic responsible mentioned in this regulation refers to the domestic enterprise legal person designated by the overseas holders to fulfill the obligations of the drug marketing authorization holder in China and jointly sustain several liability with the drug marketing authorization holder.

Article 3- Overseas holders shall designate domestic responsible person in accordance with the law and domestic responsible person shall fulfill the relevant obligations of drug marketing authorization holders within China, as well as the supervision and management activities of domestic responsible person by CNMPA, which shall be subject to these regulations. CNMPA is responsible for guiding Drug Supervision and Administration Departments of Provinces, Autonomous Regions and Municipalities to carry out supervision and management of responsible person. Drug Supervision and Administration Department of Province, Autonomous Region and Municipality are responsible for supervision and management of domestic responsible person within their respective administrative regions.

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

Article 4- Domestic responsible shall meet the following conditions simultaneously:

a. Enterprise legal person shall be established within the territory of China;

b. Having a quality management system that is suitable for fulfilling obligations of drug marketing authorization holders;

c. Having institutional personnel suitable for fulfilling obligations of drug marketing authorization holders and having specialized personnel independently responsible for management of drug quality activities;

d. Having suitable office space.

Article 5- Overseas holders shall report their designated domestic responsible person to the Drug Supervision and Administration Department of the Province, Autonomous Region or Municipality through the National Drug Business Application System before the first import and sale of drugs. Overseas holders shall upload the authorization materials of the designated domestic responsible person.

Article 6- The authorization materials for overseas holders to designate a responsible domestic person shall include the following content:

a. Name, phone number and e-mail address of the legal representative or the authorized representative. Additionally, name, phone number and e-mail address of the contact person.

b. Identity card information and name of the legal representative of the domestic responsible person, the contact person, the person in charge of the enterprise, as well as the enterprise's mailing address and contact information, organizational chart, etc.

c. Original commitment letter for joint signing of obligations between overseas holders or authorized representatives and the legal representative of the responsible person in China.

d. Notarized authorization responsibility list.

The materials (reliable electronic signatures and seals that comply with legal regulations) have the same legal effect as handwritten signatures or seals.

Article 7- For a single variety drug listed within China, the overseas holders shall designate only one responsible person in China to fulfill the obligations of drug market authorization holders. The same responsible person within China may accept the designation of different

overseas holders and different imported drug varieties. Name, address and contact of the domestic person responsible should be listed in the drug instruction.

Article 8- If the overseas holder changes the domestic responsible person, overseas holder shall report to the Drug Supervision and Administration Department of the Province, Autonomous Region or Municipality where the change is located through the national drug business application system within 15 working days after the authorization letter takes effect. If the domestic person changes the enterprise address or the contact information, he/she shall promptly report to Drug Supervision and Administration Department of Province, Autonomous Region or Municipality where the change is located through the national drug business application system. Overseas holders shall report the change of domestic person responsible for the previous year in the annual report.

Article 9- CNMPA and Drug Supervision and Administration Department of Province, Autonomous Region and Municipality share relevant information related to the domestic responsible person within the administrative regions of each province through the CNMPA data sharing platform. CNMPA promptly collects relevant information related to the domestic person responsible into the drug variety file.

Article 10- CNMPA is responsible for disclosing relevant information of responsible person within the country; in doing so, the public has the right to access it.

Article 11- The domestic responsible person and the overseas holder shall jointly fulfill the following obligations:

a. Responsible for drug quality and safety, establish a post marketing quality assurance system for drugs, ensuring continuous quality assurance and risk control capabilities;

b. Responsible for establishing and implementing a drug traceability system, ensuring the traceability of relevant marketed drugs and providing traceability information in accordance with regulations;

c. Responsible for establishing and implementation an annual drug reporting system on the production, sales, post market research, risk management and other related information of drugs in China;

d. Responsible for establishing and implementing a management system for drug post marketing changes, re-registration of drugs and handling change matters in accordance with regulations;

e. Responsible for establishing a drug surveillance system, conducting monitoring, identification, evaluation, control of adverse reactions of marketed drugs and other harmful reactions related to medication;

f. Responsible for managing post market drug recalls, quality complaints, reporting to the drug supervision and administration departments of Provinces, Autonomous Region and Municipality in accordance with regulations;

g. Submit standard substances to the China National Institute for Food and Drug Control in accordance with regulations, actively cooperate with the drug supervision and management department to organize and implement sampling and batch issuance;

h. Responsible for liaising with overseas holders, cooperating with the drug supervision and management department to conduct inspections, investigations and punishment of illegal and irregular behaviors related to overseas holders;

i. Other obligations stipulated by laws and regulations;

Article 12- Overseas holders shall be responsible for the authorization and change management of their domestic responsible person, ensuring that the domestic responsible person continue to fulfill their obligations during the drug market period.

Article 13- When applying for import registration of imported drugs for the first time, the Drug Supervision and Administration Bureau shall check whether the instructions of the imported drugs contain the information of the domestic responsible person.

Article 14- The Drug Supervision and Administration Department of Province, Autonomous Region, and Municipality shall conduct supervision and inspection of drug related activities carried out by responsible person within their administrative regions who fulfill their obligations as overseas holders in accordance with laws and regulations. Relevant units and individuals shall cooperate and shall not refuse or conceal. The Drug Supervision and Administration Department of Province, Autonomous Region, and Municipality shall establish a supervision file for responsible person within the territory, which includes information on supervision and inspection, investigation and punishment of illegal and irregular behaviors, and handling of complaints and reports. If the drug registration certificate held by the overseas holder is cancelled or revoked, the Drug Supervision and Administration Department of the Province, Autonomous Region or Municipality where the domestic responsible person is located shall be responsible for making relevant marks in the National Drug Business Application System.

Article 15- If the domestic responsible person doesn't meet the conditions stipulated in Article 4 of these regulations, the Drug Supervision and Administration Department of the Province, Autonomous Region or Municipality shall rectify within a specified time limit; If the corresponding conditions are still not met after rectification, measures such as suspending sales and imports shall be taken.

Article 16- If the responsible person within the territory neglects to fulfill the obligations stipulated in Article 11 of these regulations, resulting in potential safety hazards in imported drugs, the Drug Supervision and Administration Department of Province, Autonomous Region and Municipality directly shall take measures such as warnings, interviews, rectification within a time limit, suspension of sales or imports and promptly announce the inspection and handling results.

Article 17- The drug regulatory authorities of Provinces, Autonomous Regions, and Municipalities directly under the Central Government may formulate implementation rules in accordance with these regulations.

Article 18- This regulation shall come into effect on July 1, 2025.

Policy Interpretation of the Provisional Regulation on the Management of Designated Domestic Responsible Person by Overseas Drug Marketing Authorization Holders

1- What is the background and significance of formulating the Provisional Regulation on the Administration of Designated Domestic Responsible Person by Overseas Drug Marketing Authorization Holders?

Answer: In order to implement the *Drug Administration Law of the People's Republic of China* and the *Vaccine Administration Law of the People's Republic of China*, strengthen the management of overseas drug marketing authorization holders (hereinafter referred to as overseas holders), clarify the rights and responsibilities of overseas holders and their designated domestic responsible person (hereinafter referred to as domestic responsible person), and fully implement the main responsibility of overseas holders throughout their life cycle, the National Medical Products Administration has organized the formulation of the *Provisional Regulation on the Management of Designated Domestic Responsible Person of Overseas Drug Marketing Authorization Holders*.

In the early stage, the National Medical Products Administration compared and studied relevant laws and regulations of other countries, systematically organized the obligations and responsibilities of domestic responsible person and clarified the path for setting up domestic responsible person in China. The formulation and promulgation of the *Provisional Regulation* is conducive to further strengthening the implementation of the main responsibility of overseas produced drugs after they are listed in China and is conducive to ensuring the quality and safety of drugs. The designation of domestic responsible person doesn't involve administrative approval processes and doesn't affect the product registration of overseas holders. By strengthening post market supervision of drugs, the supervision and management of domestic responsible person can be achieved.

2- Which are the conditions and requirements for a domestic responsible person?

Answer: According to the Provisional Regulations, the responsible person within the territory of China shall meet the following conditions simultaneously:

(1) An enterprise legal person established within the territory of China;
(2) Having a quality management system that is suitable for fulfilling the obligations of drug marketing authorization holders;
(3) Personnel from institutions that are suitable for fulfilling the obligations of drug marketing authorization holders, with dedicated personnel independently responsible for drug quality management activities;
(4) Having suitable office space.

If the responsible person within the territory doesn't meet the above conditions, the Provincial Drug Supervision and Administration Department shall urge rectification within a specified time limit. For those who still don't meet the corresponding conditions after rectification, measures such as suspending sales and imports of the corresponding overseas produced drugs shall be taken. Moreover, The *Provisional Regulation* specifies that for a single drug variety listed within China, its overseas holder shall designate only one responsible person within China to fulfill the obligations of the drug marketing authorization holder. The same responsible person within China may accept the designation of different overseas holders and different imported drug varieties.

3- Which are the requirements and channels for reporting by the domestic responsible person?

Answer: Before the first import and sale of drugs, overseas holders shall report their designated domestic responsible person to the Provincial Drug Supervision and Administration Department where the domestic responsible person is located through the national drug business application system and upload the authorization materials of the designated domestic responsible person. If overseas holders change domestic responsible person, they shall report the change to the Provincial Drug Supervision and Administration Department through the National Drug Business Application System within 15 working days after the license authorization letter takes effect. Regarding overseas produced drugs that have already been marketed and sold before the implementation of the Provisional Regulation, a responsible person within the country should be designated as required and relevant materials should be reported and submitted during the transition period before the official implementation of the document.

4- How to log into the National Drug Business Application System?

Answer: New enterprise users need to first enter the National Medical Products Administration's government service portal for registration (website: https://zwfw.nmpa.gov.cn/).
If you already have a government service portal user account, you can choose "Legal Person Login" and bind it to the "Drug Business Application System". The specific operation process of reporting after system login can be found in the "Help Document" of the National Drug Business Application System (Information Collection Category), which includes the operation manual for reporting information of domestic responsible person.

5- Through which channels can the public inquire about the domestic responsible person's information?

Answer: The Provisional Regulations require that the name, address and contact information of the responsible person within the country should be listed in the drug instructions. The National Medical Products Administration is responsible for making public the relevant information of domestic responsible person designated by overseas holders and the public has the right to access it. Therefore, the public can directly view the drug instructions or log into the drug data query section on the official website of the National Medical Products Administration to search for the corresponding domestic responsible person information.

6- What are the considerations regarding the transitional period for the implementation of the Interim Provisions?

Answer: Considering that the Provisional Regulations involve adjustments to the instructions of drugs produced overseas, overseas holders need to prepare report materials. Therefore, a transition period of about 8 months is given to overseas holders to select domestic responsible person who meet the requirements according to the new regulations. Starting from July 1, 2025, overseas enterprises shall comply with the requirements of the Interim Provisions and include information on the responsible person within the country in the instructions.