Announcement of the National Medical Products Administration and the National Intellectual Property Administration of Issuance of the Implementation Measures for the Mechanism for Early Settlement of Medicinal Product Patent Disputes (for Trial Implementation)[1]

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Article 1

These Measures are formulated to protect the legitimate rights and interests of drug patent holders, encourage new drug research, and promote the development of high-quality generic drugs, thereby establishing an early resolution mechanism for drug patent disputes.

Article 2

The State Council's drug regulatory authority shall organize the establishment of the China Marketed Drug Patent Information Registration Platform, which allows drug marketing authorization holders to register patent information related to drugs approved and marketed in China.

Drugs without patent information registered on this platform shall not fall within the scope of these Measures.

Article 3

The national drug evaluation institution is responsible for establishing and maintaining the platform, and for publicly disclosing the patent information related to approved marketed drugs.

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

Article 4

Within 30 days after obtaining the drug marketing authorization certificate, the marketing authorization holder shall register the following information: drug name, dosage form, specification, marketing authorization holder, relevant patent number, patent title, patent holder, patent licensee, patent grant date and expiry date, patent status, type of patent, correlation between the drug and the claims of the patent, contact address, contact person, and contact details. If any registered information changes, it must be updated within 30 days of the change becoming effective.

The marketing authorization holder is responsible for the authenticity, accuracy, and completeness of the registered information, and shall promptly verify and record any objections received. The registered information must be consistent with the patent register, patent gazette, and the drug marketing authorization certificate. Medical use patents must correspond to the indications or therapeutic uses specified in the approved drug label. The patent protection scope must cover the technical solutions of the approved drug. Reasons for any changes to the information must be explained and publicly disclosed.

Article 5

Marketing authorization holders of chemical drugs may register the following patents on the platform: patents for the active pharmaceutical ingredient compound, pharmaceutical composition containing the active ingredient, and medical use patents.

Article 6

When a chemical generic drug applicant applies for marketing authorization, he or she shall make a statement for each related patent on the brand-name medicinal product against the patent information disclosed on the Patent Information Registration Platform for Medicinal Products Marketed in China. The statement falls into four categories:

-Type I Declaration: There is no relevant patent information for the reference listed drug on the China Marketed Drug Patent Information Registration Platform.

-Type II Declaration: The relevant patent rights recorded on the platform have either expired or been declared invalid, or the generic drug applicant has obtained a license from the patent holder to practice the relevant patents.

-Type III Declaration: The relevant patents of the reference listed drug are recorded on the platform, and the generic drug applicant undertakes not to market the generic drug applied for until the expiry of the corresponding patent rights.

-Type IV Declaration: The relevant patent rights of the reference listed drug, as recorded on the platform, are either subject to a declaration of invalidity, or the generic drug is asserted not to fall within the scope of protection conferred by those patent rights.

The generic drug applicant shall be responsible for the authenticity and accuracy of the declarations made.

Within 10 working days after the generic drug application is accepted, the national drug evaluation agency shall publicly disclose the application information and the corresponding declaration on the information platform. The generic drug applicant shall also notify the marketing authorization holder of the declaration and its supporting evidence. If the marketing authorization holder is not the patent right holder, the former shall notify the patent right holder.

In cases of a Type IV Declaration (i.e., non-infringement or invalidity), the supporting evidence shall include a comparison table of the technical solution of the generic drug and the relevant claims of the patent, along with relevant technical documentation.

In addition to providing the documents in hard copy, the generic drug applicant shall also send the declaration and supporting evidence to the electronic email address registered by the marketing authorization holder on the China Marketed Drug Patent Information Registration Platform, and retain relevant records thereof.

Article 7

If a patent holder or an interested party disputes any of the four types of patent declarations, they may, within 45 days from the date the National Drug Evaluation Agency publicly discloses the drug marketing authorization application, initiate litigation with the People's Court or request an administrative ruling from the Patent Administration Department of the State Council regarding whether the technical solution of the drug applied for falls within the scope of the relevant patent rights. If a party is dissatisfied with the administrative ruling issued by the Patent Administration Department of the State Council, they may file a lawsuit with the People's Court according to law after receiving the ruling.

Where the patent holder or interested party initiates litigation or requests an administrative ruling within the prescribed time limit, they shall submit a copy of the court's filing notice or the Patent Administration Department's acceptance notice to the National Drug Evaluation Agency within 15 working days from the date of such filing or acceptance and notify the generic drug applicant accordingly.

Article 8

Upon receipt of the case filing or acceptance notice copy from the People's Court or the Patent Administration Department of the State Council, the State Drug Regulatory Authority shall impose a nine-month waiting period on the chemical generic drug registration application. The waiting period shall commence from the date of case filing or acceptance and shall only be set once. During the waiting period, the National Drug Evaluation Agency shall not suspend the technical evaluation. If the patent holder or interested party fails to initiate litigation or request administrative ruling within the prescribed period, the State Drug Regulatory Authority shall decide on whether to approve the marketing based on the technical evaluation results and the

declaration made by the generic drug applicant; the generic drug applicant may initiate litigation or request administrative ruling according to relevant provisions.

Article 9

For chemical generic drug registration applications that trigger the waiting period, the patent holder or interested party and the generic drug applicant shall submit relevant documents, such as judgment or ruling documents, to the National Drug Evaluation Agency within 10 working days of receipt. For chemical generic drug registration applications that pass the technical evaluation, the National Drug Evaluation Agency shall take corresponding actions in conjunction with the effective judgment of the People's Court or the administrative ruling of the Patent Administration Department of the State Council as follows:

1-If it is confirmed that the application falls within the scope of the relevant patent rights, the related chemical generic drug registration application shall be transferred to the administrative approval stage before the patent term expires;

2-If it is confirmed that the application does not fall within the scope of the relevant patent rights or if the parties reach a settlement, the related chemical generic drug registration application shall proceed to the administrative approval stage;

3-If the relevant patent rights are declared invalid according to law, the related chemical generic drug registration application shall proceed to the administrative approval stage;

4-If the waiting period expires and the State Drug Regulatory Authority has not received an effective judgment, mediation document from the People's Court, or administrative ruling from the Patent Administration Department of the State Council, the related chemical generic drug registration application shall proceed to the administrative approval stage;

5-If during the administrative approval period the State Drug Regulatory Authority receives an effective judgment from the People's Court or an administrative ruling from the Patent Administration Department of the State Council confirming the application falls within the scope of relevant patent rights, the related chemical generic drug registration application shall be handled by the National Drug Evaluation Agency in accordance with the provisions of paragraph 1 of this article.

After the State Drug Regulatory Authority makes a decision to withhold approval, if the People's Court overturns the original administrative ruling, the parties reach a settlement, the relevant patent rights are declared invalid, or the patent holder or interested party withdraws the litigation or administrative ruling request, the generic drug applicant may apply to the State Drug Regulatory Authority for approval to market the generic drug, and the Authority may decide whether to grant approval.

Article 10

For chemical generic drug registration applications involving Type I or Type II declarations, the National Medical Products Administration (NMPA) shall decide whether to approve the drug for marketing based on the technical review conclusions. For applications involving Type III declarations that pass technical review, marketing approval shall be granted, but the drug may only be marketed after the expiration of the relevant patent and market exclusivity period.

Article 11

For the first chemical generic drug that successfully challenges a patent and obtains marketing approval, a market exclusivity period shall be granted. Within 12 months from the date of approval, the NMPA shall not approve the marketing of any other generic drugs of the same variety, except in cases where multiple applicants have jointly succeeded in challenging the patent.

The exclusivity period shall not exceed the remaining term of the challenged patent. During this exclusivity period, the drug evaluation agency shall continue the technical review process for other applications. For applications that pass technical review during the exclusivity period, the NMPA shall postpone administrative approval until the exclusivity period expires.

"Successful patent challenge" refers to the situation where a generic drug applicant submits a Type IV declaration, and the relevant patent is declared invalid based on the applicant's petition, thereby enabling approval of the generic drug.

Article 12

Marketing authorization holders of traditional Chinese medicines (TCM) and biological products shall register relevant patent information in accordance with Articles 2, 3, 4, and 7 of these Measures. For TCM, registrable patents include composition patents, extract patents, and medical use patents. For biological products, registrable patents include those on the sequence structure of active ingredients and medical use patents. Applicants for TCM products with the same name and formula and biosimilars shall make patent declarations in accordance with Article 6.

Article 13

For registration applications of TCM with the same name and formula, and biosimilars, the NMPA shall make approval decisions directly based on technical review conclusions. Where the people's court or the patent administrative department under the State Council confirms that the relevant technical solution falls within the scope of protection of a relevant patent, the product may only be marketed after the expiration of the corresponding patent.

Article 14

Where a chemical generic drug, traditional Chinese medicine with the same name and formula, or biosimilar has been approved for marketing, and the patent holder or interested party believes that the relevant drug infringes their patent rights, any resulting disputes shall be resolved in accordance with the Patent Law of the People's Republic of China and other applicable laws and regulations. The legally approved marketing authorization decision for the drug shall not be revoked, nor shall its validity be affected.

Article 15

Any party that submits false declarations or engages in fraudulent conduct, such as deliberately registering patents on the China Marketed Drug Patent Information Registration Platform that are unrelated to the approved drug or not of the type required to be registered, or infringes the relevant patent rights of a patent holder, or causes damage to other parties, shall bear corresponding legal liability in accordance with the law.

Article 16

These Measures shall come into force as of the date of promulgation.