Implementing Measures for Mechanism for Early Resolution of Drug Patent Disputes (Trial) (Draft for Comments)	Implementing Measures for Mechanism for Early Resolution of Drug Patent Disputes (Trial)
Article 1 ~~[Legislative Purpose]~~ To protect the legitimate rights and interests of drug patentees, encourage new drug research and promote the development of high-quality generic drugs, and establish a mechanism for early resolution of drug patent disputes.	**Article 1** The Measures is set to protect the legitimate rights and interests of drug patentees, encourage new drug research and promote the development of high-quality generic drugs, and establish a mechanism for early resolution of drug patent disputes.
Article 2 ~~[Patent Information Registration]~~ The drug regulatory and administrative department under the State Council shall establish the Patent Information Registration Platform of Marketed Drugs in China, for drug Marketing Authorization Holders ("MAHs") to register patent information related to drugs registered and approved in China, **~~and make said information public to the general public~~**. The instant measures do not apply to patent information that is not registered on the Patent Information Registration Platform ("PIRP") for Marketed Drugs in China.	**Article 2** The drug regulatory and administrative department under the State Council shall **organize and set up** the Patent Information Registration Platform of Marketed Drugs in China, for drug Marketing Authorization Holders ("MAHs") to register patent information related to drugs registered and approved in China. The Measures do not apply to **relevant** patent information that is not registered on the Patent Information Registration Platform ("PIRP") for Marketed Drugs in China.
Article 3 ~~[Platform Management]~~ The national drug review institution is responsible for establishing and maintaining the Patent Information Registration Platform for Marketed Drugs in China. **~~When applying for drug marketing, the applicant shall register the drug name, relevant patent number, patent type, patent status, patentee, Marketing Authorization Holder, expiration date of patent protection, correspondence address,~~**	**Article 3** The national drug review institution is responsible for establishing and maintaining the Patent Information Registration Platform for Marketed Drugs in China, **and publicizing the patent information of the drugs approved for marketing.**

~~**contact person, contact information and other contents by itself. For the patent related to the approved drug, the MAH may submit additional relevant patent information for supplement.**~~ ~~**The applicant or the MAH shall be responsible for the authenticity, accuracy and completeness of the patent information submitted by the applicant or the MAH.**~~ **(The deleted second and third paragraphs are merged into Article 4.)**	
Article 4 ~~[Information Management]~~ ~~During the period of drug evaluation, the applicant who has obtained the patent right may, within 30 days after the announcement of the grant of the patent right, register the patent information on the PIRP, and submit the patent information to the national drug review institution for supplementary submission. In the event of any change in the registered drug patent information, the applicant or the MAH shall, within 30 days after the change takes effect, register the change on the PIRP.~~	**Article 4** **The MAH shall, within 30 days after obtaining the Drug Registration Certificate,** register the drug name, **dosage form, specifications,** Marketing Authorization Holder, relevant patent number, **patent name**, patentee, **patent licensee, patent grant date,** expiration date of patent protection, patent status, patent type, **corresponding relationship between medicine and related patent claims**, correspondence address, contact person, contact information and other contents by itself. **In case of any change to the relevant information, the MAH shall complete the update within 30 days after such change takes effect.** The MAH shall be responsible for the authenticity, accuracy and completeness of the patent information **registered by** the MAH, **and shall verify, deal with and record the relevant oppositions received in a timely manner. The registered information shall be consistent with the relevant information in the patent register, patent gazette and drug registration certificate. The patent right for medical use shall be consistent with the indications or major functions in the instructions of the**

	pharmaceutical products approved for marketing. The protection scope of relevant patents shall cover the corresponding technical solutions of the drugs approved for marketing. In case of modifying relevant information, the reasons shall be stated and such modification shall be publicized.
Article 5 ~~[Patent Type of Registration on the Platform]~~ ~~**When an applicant for chemical drug registration submits an application for a drug marketing authorization, said applicant**~~ may register patents for pharmaceutical active ingredient compounds, patents for pharmaceutical compositions containing active ingredient(s), and pharmaceutical use patents on the PIRP.	**Article 5** **A MAH of chemical medicine** may register patents for pharmaceutical active ingredient compounds, patents for pharmaceutical compositions containing the active ingredient(s), and pharmaceutical use patents on the PIRP.
Article 6 ~~[Patent Declaration]~~ When an applicant for a chemical generic drug submits an application for a drug marketing authorization, said applicant shall, based on the patent information that has been ~~**listed**~~ on the PIRP, make a declaration on each drug patent related to the generic drug ~~**and provide the basis for said declaration**~~. The declarations are divided into four categories: Category I Declaration: There is no patent information related to the corresponding original drug on the PIRP; Category II Declaration: The patent related to the corresponding original drug recorded on the PIRP has been terminated or declared invalid; Category III Declaration: For the patent of the corresponding original drug on the PIRP, the generic drug applicant promises not	**Article 6** When an applicant for a chemical generic drug submits an application for a drug marketing authorization, said applicant shall, based on the patent information that has been **publicized** on the PIRP, make a declaration on each drug patent related to the generic drug. The declarations are divided into four categories: Category I Declaration: There is no patent information related to the corresponding original drug on the PIRP; Category II Declaration: The patent **rights** related to the corresponding original drug recorded on the PIRP have been terminated or declared invalid, **or the applicant of generic drugs has obtained relevant patent license from the patentee**; Category III Declaration: For the patent of the corresponding original drug on the PIRP, the generic drug applicant promises not

to put the generic drug on the market until the date on which such patent will expire. Category IV Declaration: The patent right recorded on the PIRP related to the corresponding original drug shall be declared invalid, or the generic drug does not fall within the protection scope of that such patent right. ~~**The generic drug applications and the corresponding declarations will be made public on the information platform of the national drug review institution.**~~	to put the generic drug on the market until the date on which such corresponding patent **right** will expire; Category IV Declaration: The patent right recorded on the PIRP related to the corresponding original drug shall be declared invalid, or the generic drug does not fall within the protection scope of that such patent right. **Applicants for generic drugs shall be responsible for the authenticity and accuracy of relevant declarations. The national drug review institution shall release the application information and corresponding declarations to the public via the information platform within 10 working days from an application for generic drugs is accepted; A generic drug applicant shall notify the MAH of the corresponding declarations and the basis thereof; where the MAH is not the patentee, the MAH shall notify the patentee of the same. Wherein if the declaration is not falling within the scope of protection of the relevant patent right, the basis for the declaration shall include the comparison table between the technical solution of the generic drug and the relevant claim of the relevant patent as well as the relevant technical materials. In addition to paper materials, applicants for generic drugs shall also send the declaration and the basis for such declaration to the email address registered by the MAH on the PIRP, and keep relevant records.**
Article 7 ~~[Objection]~~ The patentee or any interested party who has any objection to the patent declaration~~, the basis for the declaration~~ may, within 45 days from the date when the national drug review institution makes public the application for the drug marketing authorization,	**Article 7** The patentee or any interested party who has any objection to Category IV declaration may, within 45 days from the date when the national drug review institution makes public the application for the drug marketing authorization, file a lawsuit before

file a lawsuit before People's court or ~~**apply to**~~ the patent administration department under the State Council for an administrative adjudication, regarding whether the relevant technical solutions of the drug applied for marketing approval fall within the protection scope of the patent rights. If the patentee or any interested party files a lawsuit or ~~**applies**~~ for an administrative adjudication within the prescribed time limit, the patentee or the interested party shall, within ~~**10**~~ days from the date when the case is docketed ~~**or accepted**~~ by the people's court or the patent administration department under the State Council, submit a copy of the notification of acceptance to the national drug review institution. ~~**Where the patentee or an interested party fails to file a lawsuit or apply for an administrative adjudication within the prescribed time limit, the drug regulatory and administrative department under the State Council may, on the basis of the conclusion of the technical review and the declaration submitted by the generic drug applicant, directly make a decision on whether to approve the application or not.**~~	People's court or **petition** the patent administration department under the State Council for an administrative adjudication, regarding whether the relevant technical solutions of the drug applied for marketing approval fall within the protection scope of the patent rights. **Where a party concerned is dissatisfied with the administrative adjudication rendered by the State Council's patent administration department, it may institute legal proceedings in the people's court in accordance with the law upon receipt of the administrative adjudication.** If the patentee or any interested party files a lawsuit or **petitions** for an administrative adjudication within the prescribed time limit, the patentee or the interested party shall, within **15 working** days from the date when the case is docketed by the people's court or **accepted by** the patent administration department under the State Council, submit a copy of the notification of **case docket or** acceptance to the national drug review institution **and notify the generic drug applicants.**
Article 8 ~~[Stay Period]~~ ~~**From the date when the case is recorded or accepted by the people's court or the patent administration department under the State Council,**~~ the drug regulatory and administrative department under the State Council shall set up a 9-month stay period for the registration of chemical generic drugs, during which the national drug review institution shall not stop the technical review.	**Article 8** **After receiving the copy of the notice of case docket by the people's court or the notice of accepting the case by the administrative department for patent under the State Council,** the drug regulatory and administrative department under the State Council shall set up a 9-month stay period for the application of the registration of chemical generic drugs. **The stay period shall only be set once from the date on which the case is docketed by the people's court or the date on which the patent administrative department under the State Council**

	accepts the case. The national drug review institution shall not stop the technical review during the stay period. **Where the patentee or an interested party fails to file a lawsuit or petition for an administrative adjudication within the prescribed time limit, the drug regulatory and administrative department under the State Council will, on the basis of the conclusion of the technical review and the declaration submitted by the generic drug applicant, directly make a decision on whether to approve the application or not. Applicants for generic drugs may file a lawsuit or petition for administrative adjudication in accordance with relevant provisions.**
~~**Article 10 [Examinations and Approvals by Category]**~~ With regard to a chemical generic drug registration application ~~**with Category IV declaration, if the patentee or any interested party, within 45 days from the date when the national drug review institution makes public the application for the drug marketing authorization, files a lawsuit before a people's court or apply to the patent administration department under the State Council for an administrative adjudication, regarding whether the relevant technical solutions of the generic drug fall within the protection scope of the patent rights or not,**~~ the patentee or the interested party shall, within 10 days upon receiving judgment or decision, submit the ~~**judgment or the decision**~~ to the national drug review institution. With regard to the chemical generic drug registration application that has passed technical review, the national drug review institution shall process the application in view of the judgment of the people's court or the administrative adjudication of the	**Article 9** With regard to a chemical generic drug registration application that triggers stay period, the patentee, the interested party **or the applicant for a chemical generic drug** shall, within 10 **working** days upon receiving judgment or decision, submit the **relevant documents** to the national drug review institution. With regard to the chemical generic drug registration application that has passed technical review, the national drug review institution shall process the application in view of the **effective** judgment of the people's court or the administrative adjudication of the patent administration department under the State Council, as follows: (I) If the relevant technical solutions are determined to fall within the protection scope of the relevant patent rights, the chemical generic drug **registration** application shall be forwarded to the administrative review and approval process before the expiration

patent administration department under the State Council, as follows: (I) If the relevant technical solutions are determined to fall within the protection scope of the relevant patent rights, the chemical generic drug application shall be forwarded to the administrative review and approval process ~~**20 workdays**~~ before the expiration of the patent right; (II) If the relevant technical solutions are determined not to fall within the protection scope of the relevant patent rights, or both parties reach a settlement, the chemical generic drug application shall be forwarded to the administrative review and approval process in accordance with the procedures; (III) If the relevant patent right ~~**is declared invalid**~~, the chemical generic drug application shall be forwarded to the administrative review and approval process in accordance with the procedures; (IV) ~~**If the people's court or the patent administration department under the State Council has not made an effective judgment or administrative adjudication, or has not issued a mediation,**~~ after the stay period, the chemical generic drug application shall be forwarded to the administrative review and approval process in accordance with the procedures. (V) Where, during the period of administrative review and approval, the drug regulatory and administrative department under the State Council receives a judgment of the people's court or an administrative adjudication of the patent administration department under the State Council, determining that the relevant technical solutions fall within the protection scope of the relevant patent rights, the drug regulatory and administrative department under the State Council shall turn over the relevant chemical	of the patent right; (II) If the relevant technical solutions are determined not to fall within the protection scope of the relevant patent rights, or both parties reach a settlement, the chemical generic drug **registration** application shall be forwarded to the administrative review and approval process in accordance with the procedures; (III) If the relevant patent right **is invalidated by the law**, the chemical generic drug **registration** application shall be forwarded to the administrative review and approval process in accordance with the procedures; (IV) **Where the drug regulatory and administrative department under the State Council has not received the effective judgment or mediation decision of the people's court or the administrative adjudication of the patent administrative department under the State Council** after the stay period, the chemical generic drug **registration** application shall be forwarded to the administrative review and approval process in accordance with the procedures; (V) Where, during the period of administrative review and approval, the drug regulatory and administrative department under the State Council receives an **effective** judgment of the people's court or an administrative adjudication of the patent administration department under the State Council, determining that the relevant technical solutions fall within the protection scope of the relevant patent rights, the drug regulatory and administrative department under the State Council shall turn over the relevant chemical generic drug **registration** application to the national drug review institution for processing the application in accordance with the provisions of item I, Paragraph **II** of this

generic drug application to the national drug review institution for processing the application in accordance with the provisions of Paragraph I of this Article. If, after the drug regulatory and administrative department under the State Council decides to suspend the approval ~~**in accordance with a judgment of the people's court or an administrative adjudication of the patent administration department under the State Council,**~~ the people's court overturns the original ~~**judgment or**~~ administrative adjudication ~~**in the final instance**~~, the generic drug applicants may apply for approval of the generic drug application to the drug regulatory and administrative department under the State Council, which ~~**will**~~ make a decision on whether to approve the application ~~**according to the technical review conclusion and the people's court's final judgment**~~.	Article. If, after the drug regulatory and administrative department under the State Council decides to stay the approval, the people's court overturns the original administrative adjudication, **the two parties reach a settlement, the related patent right is declared invalid, or the patentee or any interested party withdraws the request for litigation or administrative adjudication,** the generic drug applicants may apply for approval of the generic drug application to the drug regulatory and administrative department under the State Council, which **may** make a decision on whether to approve the application.
~~**Article 9 [Examinations and Approvals by Category]**~~ With regard to a chemical generic drug registration application with Category I or II declaration, the drug regulatory and administrative department under the State Council shall make a decision on whether to approve the application or not based on the conclusion of technical review; With regard to a chemical generic drug registration application with Category III declaration, which has passed technical review, a decision of approval can be made ~~**with a note that the generic drug should not be marketed until the date on which the patent rights will expire**~~.	**Article 10** With regard to a chemical generic drug registration application with Category I or II declaration, the drug regulatory and administrative department under the State Council shall make a decision on whether to approve the application or not based on the conclusion of technical review; With regard to a chemical generic drug registration application with Category III declaration, which has passed technical review, a decision of approval can be made. **The drugs concerned shall only be marketed after the expiration of the corresponding patent term and market exclusivity period.**
Article 11 ~~[Encouragement Policy]~~ For the chemical generic drug that is not only the first to successfully challenge the patent but also the first to be approved	**Article 11** For the chemical generic drug that is not only the first to successfully challenge the patent but also the first to be approved

for marketing, a market exclusivity period shall be granted, during which the drug regulatory and administrative department under the State Council shall not approve the marketing of any generic drug of the same variety within 12 months from the date of approval of the drug, and the market exclusive period shall not exceed the patent term of the challenged drug. During the exclusive period of the market, the national drug review institution will not stop the technical review. The chemical generic drug registration application that has passed technical review shall be forwarded to the administrative review and approval process ~~**20 working days**~~ before the expiration of the market exclusivity period.	for marketing, a market exclusivity period shall be granted, during which the drug regulatory and administrative department under the State Council shall not approve the marketing of any generic drug of the same variety within 12 months from the date of approval of the drug **except for successful joint patent challenges**. The market exclusivity period shall not exceed the patent term of the challenged drug. During the exclusive period of the market, the national drug review institution will not stop the technical review. The chemical generic drug registration application that has passed technical review shall be forwarded to the administrative review and approval process before the expiration of the market exclusivity period. **The successful patent challenge means that the applicant of chemical generic drugs submits Category IV declaration, wherein the invalidation request is submitted according to the declatation, and relevant patent right is declared invalid accordingly, thus enabling the generic drugs to be approved for marketing.**
Article 12 ~~[Processing by Classification]~~ ~~**Applicants for marketing approval**~~ of ~~**biological products and**~~ traditional Chinese medicines shall comply with Articles 2, 3, 4, ~~**6,**~~ and 7 of this Measure for registering relevant patent information~~**, making declarations**~~, etc. ~~**For biological products, patents concerning sequence structure can be registered, and**~~ Traditional Chinese medicines may register patents concerning Chinese medicine composition, Chinese medicine extract, and pharmaceutical use.	**Article 12** **The MAH** of traditional Chinese medicines **and biological products** shall comply with Article 2, Article 3, Article 4, and Article 7 of this Measures for registering relevant patent information, etc. Traditional Chinese medicines may register patents concerning Chinese medicine composition, Chinese medicine extract, and pharmaceutical use. **Biological products may register active ingredients sequence structure patents and pharmaceutical use patents.** **Applicants for traditional Chinese medicines of the same name and prescription and bio-similar drugs shall make the**

	relevant patent declaration in accordance with Article 6 of this Measures.
Article 13 ~~[Processing by Classification]~~ With regard to a registration application of ~~a biosimilar or~~ Chinese medicine with the same name and formulation, the drug regulatory and administrative department under the State Council shall, on the basis of the conclusion of the technical review, directly make a decision on whether to approve the application or not. ~~**If the patentee or any interested party files a lawsuit before people's court or apply to the patent administration department under the State Council for an administrative adjudication, regarding whether the relevant technical solutions of the biosimilar or Chinese medicine fall within the protection scope of the relevant patent rights, within 45 days from the date when the national drug review institution makes public the application for the drug marketing authorization, and**~~ the people's court or the patent administration department under the State Council determines that the relevant technical solutions fall within the protection scope of the relevant patent rights ~~**before the completion of the administrative approval procedure for the drug, the drug regulatory and administrative department under the State Council shall make a decision of approval after the technical review has been passed, with a note that**~~ the drug should not be marketed until the date on which the patent rights will expire.	**Article 13** With regard to a registration application of traditional Chinese medicine with the same name and prescription and **a biosimilar**, the drug regulatory and administrative department under the State Council shall, on the basis of the conclusion of the technical review, directly make a decision on whether to approve the application or not. Where the people's court or the patent administration department under the State Council determines that the relevant technical solutions fall within the protection scope of the relevant patent rights, the **relevant** drug should not be marketed until the date on which **the corresponding** patent rights will expire.
Article 14 ~~[Means of Relief]~~ After a generic drug is approved, if the patentee believes that the ~~**generic**~~ drug infringes its patent rights and causes a dispute, the	**Article 14** After a **chemical** generic drug, **a traditional Chinese medicine with the same name and prescription or a biosimilar, etc.** is

dispute shall be resolved in accordance with the provisions of the Patent Law and other laws and regulations. A decision on the marketing approval of the drug according to the laws and regulations shall not be revoked, and its effectiveness shall not be affected.	approved for marketing, if the patentee or **interested party** believes that the **relevant** drug infringes its patent rights and causes a dispute, the dispute shall be resolved in accordance with the **relevant** provisions of the Patent Law of **the People's Republic of China** and other laws and regulations. A decision on the marketing approval of the drug according to the laws and regulations shall not be revoked, and its effectiveness shall not be affected.
Article 15 ~~[Subject Responsibility]~~ **~~Applicants and their agents~~** who **~~intentionally~~** submit false declarations or **~~intentionally register other unrelated patents on the PIRP shall be subject to joint disciplinary punishment for dishonesty in accordance with the laws, and the applicants shall not apply for registration of the same drug again within one year; any violation of relevant laws and regulations shall be dealt with in accordance with the law; any infringement of the relevant patent rights of the patentee shall be subject to corresponding legal liability.~~**	**Article 15** **Anyone** who employs trickery, such as submiting false declarations, **intentionally registers a patent whose protection scope is irrelevant to the drugs approved for marketing or which does not belong to the patent type that should be registered on the PIRP, or infringes the relevant patent rights of a patentee or any other loss incurred to a party concerned, shall be subject to corresponding legal liability according to the law.**
Article 16 ~~[Implementation Time]~~ The instant measures shall come into force as of ~~**XX**~~.	**Article 16** The Measures shall come into force as of **the date of issue**.