China Insight

Highlights on the Revised Drug Registration Administrative Measures

Dear Sir or Madam,

The revised *Drug Registration Administrative Measures* promulgated by the State Administrative for Market Regulation of the People's Republic of China on 22 January 2020 will enter into force in less than one month (i.e. as of 1 July 2020). We highlighted some major changes in below newsletter.

Kind regards,
CMS, China

The revised *Drug Registration Administrative Measures* (the "**Revised Measures**") promulgated by the State Administrative for Market Regulation (the "**SAMR**") of the People's Republic of China (the "**PRC**") on 22 January 2020 will enter into force in less than one month (i.e. as of 1 July 2020).

Upon the entry into force of the *Revised Measures,* the *Drug Registration Administrative Measures* promulgated on 10 July 2007 and effective as of 1 October 2007 (the "**Previous Measures**") shall be abolished as of 1 July 2020 accordingly. The SAMR also published an announcement on 30 March 2020 regarding some transitional issues between the *Previous Measures* and the *Revised Measures* (the "**Notice [2020] No. 46**").

The *Revised Measures* are modified to implement new changes set forth in the revision of the *PRC Drug Administration Law* which was extensively revised in 2019[1] (the "**Revised Drug Administration Law**"). Besides, in light of the *Opinions on Deepening the Reform of Evaluation and Approval System and Inspiring Innovation of Drugs and Medical Devices* (the "**Opinions**") promulgated by the Central Committee of the Communist Party of China and the General Office of the State on 8 October 2017 for the purpose of encouraging the drug and medical device innovation in China, besides the introduction of Market Authorization Holder (the "**MAH**") regime, the *Revised Drug Administration Law* has also introduced a series of new procedures to improve the effectiveness of drug examination, such as implied approval of clinical trial, conditional approval, priority approval, etc.

We highlighted some major changes as follows:

1. Update related to MAH regime

Following the introduction of MAH regime by the *Revised Drug Administration Law*, the *Revised Measures* are updated accordingly.

- According to Article 9 of the *Revised Measures*, the applicant shall be the enterprise or research institution which can bear relevant legal liabilities.

- According to Article 9 of the *Revised Measures*, the foreign applicant shall designate a Chinese enterprise as its agent to conduct the relevant formalities issues. Such clause also expressly confirms that a foreign

enterprise can act as an MAH.

– According to Article 78 of the *Revised Measures*, the transfer of market authorization is possible and shall be subject to the approval by way of supplemental application. This clause confirms the possibility of transfer of market authorization.

– There are no detailed provisions regarding the exact conditions and requirements of the research institution to act as the MAH in the *Revised Measures*, but we noticed such requirements are actually stipulated in the *Administrative Measures on Supervision of Pharmaceutical Manufacturing* promulgated by the NMPA[2].

2. Cancellation of New Drug Certificate and Imported Drug Registration Certificate

According to the *Previous Measures*, the drug application includes applications for registration of new drugs, generic drugs, imported drugs and the supplemental application thereof, as well as the application for renewal. According to the *Revised Measures*, the drug application includes the applications for clinical trial, market authorization of drug, renewal and the supplemental application thereof. The definition of new drugs and imported drugs are removed from the *Revised Measures*.

a) Cancellation of the term "new drug"

Accordingly, there is no so called "New Drug Certificate" any more and an MAH will be granted a Drug Registration Certificate. We further noticed that, the whole chapter of "New Drug Application and Approval" in the *Previous Measures* has been removed, and the relevant clauses regarding the special administration and protection for new drug, such as monitoring period, have also been removed accordingly.

According to the *Notice on The Issuance of The Provisions for Registration of Drug Technology* effective as of 19 August 2009, drug approvals can be transferred through transfer of technologies related to new drug or new drug at the phase of monitoring period. Now, with the cancellation of such new drug and monitoring period by the *Revised Measures*, the above technology transfer regulation needs to be modified as well. It is questionable whether such technology transfer regulation will be totally abolished or just modified according to the *Revised Drug Administration Law.* This issue is important because some applications in the past may have already submitted through technology transfer procedure. According to the *Notice [2020] No. 46*, the application which is accepted before the implementation of the *Revised Measures*, i.e., 1 July 2020, shall be examined according to the old rules (i.e., the *Notice on The Issuance of The Provisions for Registration of Drug Technology)*. However, since the technology transfer will take a long time, there are cases where the technology transfer agreement is signed, but the application cannot be submitted prior to 1 July 2020, which implies that the new procedures as set forth in the *Revised Measures* should be applied. In such cases, the signed agreement would have to be thoroughly redone because the contractual obligations and the regulatory formalities need to be modified.

Also, the New Drug Certificate is also mentioned in the high technology companies application for 15% corporate income tax. According to the *Revised Measures*, the drugs can be classified as Innovation Drugs or Improved New Drugs. Whether or not the Drug Registration Certificate issued for the Innovation Drug and/or Improved New Drugs can be considered as a replacement of the New Drug Certificate by the tax bureau needs to be further checked.

b) Cancellation of the term "Imported Drug Registration Certificate"

According to the *Previous Measures*, the approved imported drug will be subject to an Imported Drug Registration Certificate. According to the *Revised Measures*, the approved imported drug will be subject to a Drug Registration Certificate, and there is no so called "Imported Drug Registration Certificate" any more. The official interpretations of the NMPA explains that in order to be consistent with the international practices, imported drugs shall be subject to the same examination standard and quality requirements with domestic drugs.

3. Implied approval of clinical trial

According to Article 30 of the *Previous Measures*, the clinical trial shall be subject to the approval of the China Food and Drug Administration (the "**CFDA**", now named as "NMPA"). Further, according to the *Previous Measures*, clinical trial can only be conducted upon relevant approval.

According to Article 23 of the *Revised Measures*, after the application of clinical trial is accepted by the Center for Drug Evaluation (the "**CDE**"), the decision shall be made within 60 days[3], otherwise, it shall be deemed as approval granted, and the applicant can conduct the clinical trial according to the clinical trial plan submitted.

The implied approval of clinical trial was introduced by the *Announcement of the State Drug Administration on Adjusting Evaluation and Approval Procedures for Clinical Trial for Drugs* effective as of 24 July 2018, and has been further confirmed by the *Revised Drug Administration Law*. Accordingly, the *Revised Measures* further implement such procedure.

4. Associated Approval

According to Article 14 of the *Revised Measures*, the chemical active pharmaceutical ingredients (the "**API**"), pharmaceutical excipients, packaging materials and containers in direct contact with drug shall be subject to the Associated Approval. During the approval of pharmaceutical preparations, the chemical APIs shall be reviewed and approved together, and relevant pharmaceutical excipients, packaging materials and containers in direct contact with drugs shall also be reviewed.

The Associated Approval was introduced by the *Announcement on Adjusting Matters relating to the Evaluation and Approval of Active Pharmaceutical Ingredients, Pharmaceutical Excipients and Pharmaceutical Packaging Materials* effective as of 25 November 2017, and further improved by the *Announcement of the National Medical Products Administration on Matters relating to Further Improvement to the Correlated Evaluation, Examination, Approval and Regulation of Drug* effective as of 15 August 2019. Such Associated Approval has also been stipulated in the *Revised Drug Administration Law*. Accordingly, the Revised Measures further implement such procedure.

5. Accelerated procedures for drugs registration

In light of encouraging drug development and research and innovation set forth by the *Opinions*, the *Revised Drug Administration Law* has introduced a series of procedures for the acceleration of drug registration, such as the procedures for Breakthrough Therapy Designation (the "**BTD**") drugs, conditional approval, priority approval and specific approval. The *Revised Measures* further implement these procedures accordingly.

According to the *Previous Measures*, there is also a so called fast track procedure named as Special Approval. Such Special Approval has been removed in the *Revised Measures*.

The comparison between the above-mentioned procedures (i.e., (a) the acceleration procedures as set forth in the *Revised Measures* and (b) the Special Approval as set forth in the *Previous Measures)* are described as follows:

	Scope	**Procedure**
BTD drugs	Innovative drugs or modified new drugs, etc., which are to be used during drug clinical trials for the prevention and treatment of diseases that seriously endanger life or seriously affect the quality of life, for which there is no effective measure of prevention and treatment or, compared with existing measures of treatment, there is certain sufficient evidence proving the obvious clinical advantages. *(Article 59 of the Revised Measures)*	• The applicant may apply to the CDE for communication at the critical phase of the drug clinical trial, and the CDE shall arrange review personnel to communicate; and • The applicant may submit phased research materials to the CDE, which shall put forward opinions or proposals on the research scheme at the next step on the basis of the existing research materials and send them to the applicant. *(Article 61 of the Revised Measures)*
Conditional Approval	• The drugs are used for treatment of diseases that seriously endanger life and have no effective measure of treatment, and the data of drug clinical trials can prove the efficacy and forecast the clinical value of the drugs; • the drugs are urgently needed for public health, and the data of drug clinical trials can prove the efficacy and forecast the clinical value of the drugs; or • vaccines are urgently needed to deal with major public health emergencies or other vaccines which the National Health Commission deems to be urgently	The applicant who applies for conditional approval shall communicate with the CDE about the conditions for marketing with conditional approval and the research work to be completed after marketing, among others, and submit an application for market authorization after making confirmation through communication. *(Article 64 of the Revised Measures)*

	needed, and it is assessed that the benefits thereof outweigh the risks therein. *(Article 63 of the Revised Measures)*	
Priority Approval[4]	• Drugs in short supply in urgent clinical need, innovative drugs and modified new drugs for the prevention and treatment of serious infectious diseases, rare diseases and other diseases; • Pediatric drugs of new varieties, dosage forms and specifications that meet the physiological characteristics of children; vaccines urgently needed for disease prevention and control and innovative vaccines; • Drugs included in the procedures for BTD drugs; • Drugs meeting the conditions for conditional approval; and other circumstances for priority review and approval stipulated by the NMPA. *(Article 68 of the Revised Measures)*	• The time limit for review with respect to applications for market authorization shall be shortened to **130 days[5];** • The time limit for review with respect to orphan drugs in urgent clinical need which have been marketed overseas but have not yet marketed in China shall be shortened to **70 days**; • Priority shall be given to those applications related to verification, inspection and approval of generic name; and • Supplementary technical materials may be submitted upon confirmation through communication. *(Article 70 of the Revised Measures)*
Specific Approval	In the case of any threatening or actual public health emergency, the NMPA may legally decide to implement special approval of drugs needed for the prevention and control of such public health emergency. *(Article 72 of the Revised Measures)*	The circumstances, procedures, time limit and requirements for special approval, among others, shall be subject to the procedures for specific approval of drugs. *(Article 73 of the Revised Measures)*
Special Approval (*Previous Measures*)	• Effective ingredients extracted from plants, animals, minerals and other substances as well as preparations thereof, and the newly discovered ingredients and preparation thereof, which have not been marketed in China; • Chemical raw material drugs and preparations thereof, and biological products that have not been approved to be marketed inside or outside China; • New drugs used for the curing of diagnosis and prevention of AIDS, cancer, rare disease, and other diseases that have distinct clinical advantages; or • New drugs used for the curing of diagnosis and prevention of diseases without effective treatment. *(Article 45 of the Previous Measures)*	The procedure for special approval shall be separately formulated. *(Article 45 of the Previous Measures)*

6. Data protection

According to the *Previous Measures*, the application of drug registration which uses the unauthorized clinical data or other data which has already been submitted by other previous applicant shall not be approved for a period up to 6 years upon the relevant approval. Such data protection has been removed in the *Revised Measures*.

However, we can still find the relevant clauses regarding the above-mentioned data protection in the *Implementing Regulations of the Drug Administration Law* revised and effective as of 2 March 2019 (the "Implementation Regulations"). Please note that, the *Implementation Regulations* have not been revised according to the *Revised Drug Administration Law*. It is uncertain whether or not the relevant clauses regarding the above-mentioned data protection will be kept or not in the revision of the *Implementation Regulations* which

will definitely be made in the near future.

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[1] For details, please refer to the newsletter **Revised Drug Administration Law** dated 8 October 2019.

[2] For details, please refer to the newsletter **Highlights on the Administrative Measures on Supervision of Pharmaceutical Manufacturing** dated 3 June 2020.

[3] According to Article 150 of the *Previous Measures*, the time limit for the approval of clinical trial for new drugs is 90 days, and 80 days for the drugs which are subject to the Special Approval.

[4] The Priority Approval was introduced by the *Circular related to the Opinions of the China Food and Drug Administration on Clearing the Backlog of Drug Registration Application and Performing Prioritized Review and Approval (Shi Yao Jian Yao Hua Guan [2016] No. 19)* effective as of 24 February 2016. Such Circular was abolished. But the scope of the drugs subject to the Priority Approval was extended by the *Opinions on Encouraging the Prioritized Evaluation and Approval for Drug Innovation* effective as of 21 December 2017.

[5] The time limit of a normal procedure is 200 days (Article 96 of the *Revised Measures*).

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