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Revised Drug Administration Law

Dear Sir or Madam,

Please find below our update on Revised Drug Administration Law in China.

Kind regards,
CMS, China

On 26 August 2019, the Standing Committee of the National People's Congress of the People's Republic of China (the "**PRC**") promulgated the revised *PRC Drug Administration Law* (the "**Revised Drug Administration Law**"). The *Revised Drug Administration Law* will come into effect on 1 December 2019.

The *Revised Drug Administration Law* has altogether twelve chapters, i.e., general provisions, drug research and registration, drug market authorization holder, drug manufacturing, drug distribution, drug-related affairs management in medical institutions, post-market drug management, drug pricing and advertising, drug reserve and supply, supervision and management, legal liabilities, etc., with in total 155 articles.

Background of the revision

After the *PRC Drug Administration Law* was firstly promulgated in 1984, it was comprehensively revised in 2001. Afterwards, it has been partially amended in 2013 and 2015 respectively. This revision made in 2019 is considered as the second comprehensive revision of the *PRC Drug Administration Law* since 2001.

Before the *Revised Drug Administration Law* is finally promulgated, it has gone through several arounds of discussions and changes on the draft of the revision/amendments since 2015.

The *Opinions on Deepening the Reform of Evaluation and Approval System and Inspiring Innovation of Drugs and Medical Devices* (the "**Opinions**") was 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. Following the esprit of the *Opinions*, the China Food and Drug Administration (the "**CFDA**")[1] published the *Amendments to PRC Drug Administration Law (Draft version for opinions)* on 23 October 2017. According to this draft, it was only intended to make several amendments to the current version of the *PRC Drug Administration Law* revised and effective as of 25 April 2015 (the "**Drug Administration Law (Version 2015)**"). The amendments were mainly forced on the drug innovation issues based on the *Opinions*. However, during the course of discussion and examination of the draft of the amendment, the vaccine accidents which happened in 2018 drew the attention of the State to the increasing importance of people's safety and necessity of enforcement of drug supervision and administration. Thus, a comprehensive revision of the *PRC Drug Administration Law* became necessary. At the time of second rounds of discussion and examination by the Standing Committee of the 13th National People's Congress on 20 April 2019, the draft was changed from a partial amendment into a

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comprehensive revision. After the third around of examination and discussion by the 12 session of the Standing Committee of the 13th National People's Congress on 22 August 2019, the *Revised Drug Administrative Law* was officially adopted.

Since the *Revised Drug Administration Law* was promulgated, the *Implementing Regulations of the Drug Administration Law of the PRC* (the "**Implementing Regulations**") which were made based on the *Drug Administrative Law (Version 2015)* shall also be amended/revised.

We summarize its main content and highlights of the *Revised Drug Administration Law* as below:

1. Introduction of the MAH regime

The General Office of the State promulgated the *Circular of the General Office of the State Council on Issuing the Pilot Program for the Drug Marketing Authorization Holder Regime* (the "**Plan**") on 26 May 2016. As of the promulgation of the *Plan*, the pilot regime of the MAH has been implemented in ten pilot areas in China[2] for a pilot period of four years[3]. Now, by being officially introduced into the *Revised Drug Administration Law*, the MAH regime will become a national regime on 1 December 2019.

The *Revised Drug Administration Law* has one special chapter for the MAH regime (Chapter 3 Drug Market Authorization Holder) which has the following highlights:

1) According to Article 30 of the *Revised Drug Administration Law*, the MAH refers to the enterprise or drug research institution or other entity, which obtains a drug registration certificate. According to the pilot regime as set forth by the *Plan*, the individual scientific researcher can also become the MAH. However, according to the wording of the *Revised Drug Administration Law*, the physical person cannot be allowed to be a MAH anymore;

2) According to Article 32 of the *Revised Drug Administration Law*, the mandated manufacturing of drug by the MAH to another drug manufacturing enterprise is allowed, except for ***blood product, narcotic drug, psychotropic drug, toxic drug for medical use or pharmaceutical precursor chemical***;

   Compared with the relevant regulations before the *Revised Drug Administration Law*, the changes are as follows:

Drug subject to mandated manufacturing	***Status before the Revised Drug Administration Law***	***Revised Drug Administration Law***
Blood product	*Prohibited*[4]	*Prohibited*
Narcotic drug	*No clear prohibition clause*[5]	*Prohibited*
Psychotropic drug	*No clear prohibition clause*[6]	*Prohibited*
Toxic drug for medical use	*No clear prohibition clause*[7]	*Prohibited*
Pharmaceutical precursor chemical	*Prohibited*[8]	*Prohibited*
Vaccines	*Prohibited*	***Allowed***

   According to Article 10 of the *Implementing Regulations*, the vaccines shall not be subject to the mandated manufacturing. Such prohibited will be deleted by the *PRC Vaccines Administration Law*[9] promulgated on 26 August 2019 and to be effective as of 1 December 2019;

3) The *Revised Drug Administration Law* further specifies that the MAH can be a foreign enterprise. The foreign MAH shall designate a Chinese enterprise legal person to fulfill the obligations of the MAH on behalf of the foreign MAH. The foreign MAH and the designated Chinese enterprise legal person shall bear joint and several liabilities. This means, the foreign enterprise will have the chance to be deeply involved in this MAH regime, such as transfer of the imported drug certificate to a Chinese MAH;

4) According to Article 40 of the *Revised Drug Administration Law*, the transfer of market authorization is allowed. According to the *Plan*, the change of holder of a MAH is allowed but should be subject to the application of change of holder. Compared with the term "change of holder" as used in the *Plan*, the *Revised Drug Administration Law* confirms the nature of transfer of market authorization, which is more logical.

The introduction of the MAH regime is a significant progress in the development of the *PRC Drug Administration*

Law. However, as a new regime, the MAH regime still needs to be further clarified and improved, especially regarding the allocation of liabilities between the MAH and the mandated manufacturing enterprise. According to Article 30 of the *Revised Drug Administration Law*, the MAH shall be responsible for laboratory drug trial, clinical drug trial, drug manufacturing and distribution, post-market drug research, monitoring, reporting and handling of adverse event to drug, etc. Other entities and individuals engaging in drug research, manufacturing, distribution, storage, transport, use and other activities shall assume corresponding responsibilities in accordance with the law. We understand that, without a clear allocation, the MAH and the mandated manufacturing enterprise should bear joint and several liabilities. There is no further stipulation in the *Revised Drug Administration Law* regarding the exact conditions and requirements of the research institution to act as the MAH. Thus, it might be a concern that the research institution acting as a MAH may not have sufficient financial capacity to bear the relevant liabilities as a main responsible party. On the other side, the mandated manufacturing enterprise who should have sufficient financial capacity but with relatively low profit margin and limited functions, should not bear too much liabilities according to the principle of fairness and transfer pricing rules. How to balance the allocation of liabilities between the MAH and the mandated manufacturing enterprise to ensure the efficient undertaken of liabilities should be a question to be solved.

2. Cancellation of the GMP certificate and the GSP certificate

In the *Revised Drug Administration Law,* the relevant provisions regarding the GMP[10] certificate have been removed, and the drug manufacturing enterprise does not need to apply for the GMP certificate any more. Note that according to the *Drug Administration Law (Version 2015),* the manufacturing enterprise shall apply for the GMP certificate before it can conduct any drug manufacturing activities. Such cancelation of the GMP certificate by the *Revised Drug Administration Law* is considered as a change which will impact the pharmaceutical industry the most comparing with other changes made in the *Revised Drug Administration Law*. In practice, there are many operations closely related to or relay on the GMP certificate, such as the GMP certificates used for the purpose of manufacturing of samples for clinical trial and to the drug which has passed the clinical trial during the application for drug registration. However, this is no further clarification in the *Revised Drug Administration Law* on how to handle such issues after the cancellation of the GMP certificate. This point needs to be further clarified.

Even though the GMP certificate will be cancelled, the drug manufacturing enterprise shall still meet the GMP standard. According to Article 43 of the *Revised Drug Administration Law*, the drug manufacturing enterprise shall abide by the GMP standards, and shall establish a sound good manufacturing system to ensure the continuous compliance of drug manufacturing with statutory requirements throughout the whole process. In violation of such requirement, the drug manufacturing enterprise may be imposed a fine up to RMB 2,000,000. The legal representative, main person-in-charge, direct person-in-charge and other responsible person of the aforesaid enterprise shall also be imposed a fine up to 50% of the unlawful income during the violation period, and shall be prohibited from engaging in drug manufacturing and trading activities for a period from ten years to the whole life. Compared with the *Drug Administration Law (Version 2015)*, the punishment becomes much stricter[11].

Instead of granting to the drug manufacturing enterprise the GMP certificate as proactive supervision measure, the drug administrative authority will be forced in the future on the post supervision of drug manufacturing. It is possible that the unannounced inspection will be more frequent and becomes the main post supervision measure to ensure the compliance of the drug manufacturing. Since the proactive supervision approach is changed into the post supervision approach, it implies that the duties of complying with GMP standards will be transferred from the FDA to the MAH and drug manufacturer.

Also, the GSP[12] certificate will also be cancelled by the *Revised Drug Administration Law*. The drug trading company does not need to apply for the GSP certificate any more. According to Article 53 of the *Revised Drug Administration Law*, a drug trading company shall abide by the GSP standards. In violation of GSP standards, the drug trading company will be imposed a fine up to RMB 2,000,000. The legal representative, main person-in-charge, direct person-in-charge and other responsible person of the aforesaid company shall also be imposed a fine up to 50% of the unlawful income during the violation period, and shall be prohibited from engaging in drug manufacturing and trading activities for a period from ten years to the whole life.

3. Change of definition of fake drug and sub-standard drug

Compared with the *Drug Administration Law (Version 2015),* the definition of fake drug and sub-standard drug are changed by the *Revised Drug Administration Law* as follows:

	Revised Drug Administration Law	***Drug Administration Law (Version 2015)***
Fake drug	1) *The ingredients in the drug are*	1) *The ingredients in the drug are different*

	different from those specified by the national drug standards; 2) *A non-drug substance is simulated as a drug or one drug is simulated as another;* 3) *Degenerated drug;* 4) *The indication or duction indicated are beyond the specified scope.* *(Article 98)*	*from those specified by the national drug standards;* 2) *A non-drug substance is simulated as a drug or one drug is simulated as another;* 3) *Its use is prohibited by the provisions of the drug regulatory department under the State Council;* 4) *It is produced or imported without approval, or marketed without being tested, as required by the Law;* 5) *It is deteriorated;* *it is contaminated;* *it is produced by using crude drugs without approval numbers as required by the Law;* 6) *The indications or functions indicated are beyond the specified scope.* *(Article 48)*
Sub-standard Drug	1) *The quantity of the ingredients in the drug are different from these specified by the national drug standards;* 2) *Polluted drug; drug without expiration date or such date being changed;* 3) *Drug without approval number or such number being changed;* • *drug beyond the expiration date**;*** • *drug with unapproved preservative or ingredients. (Article 98)*	1) *A drug with content not up to the national drug standards is a substandard drug;* 2) *The term of validity is not indicated or is altered;* 3) *The batch number is not indicated or is altered;* *it is beyond the term of validity;* 4) *No approval is obtained for the packaging material or container in direct contact with drugs;* 5) *Colorants, preservatives, spices, flavorings or other accessories are added without authorization;* 6) *Other cases where the drug standards are not conformed to* *(Article 49)*

According to the new definition as set forth by the *Revised Drug Administration Law*, we can see that the determination of fake drug or sub-standard drug will be forced on the effectiveness and quality of the drug itself. The drug manufactured without the approval/license will not be judged as fake drug or sub-standard drug any more. This does not mean that the supervision on the non-compliance of manufacturing of drug will be loosened in the future. On the contrary, the non-compliance of manufacturing of drug will be confronted with stricter administrative punishment according to the *Revised Drug Administration Law*[13].

4. Severe administrative punishment

The *Revised Drug Administration Law* sets forth stricter administrative penalties regarding the violation of the *Revised Drug Administration Law*. We compare below the administrative penalties to be imposed for the manufacturing and sales of fake drug and sub-standard drug in the *Revised Drug Administration Law* and the *Drug Administration Law (Version 2015)*.

	Revised Drug Administration Law	***Drug Administration Law (Version 2015)***
Manufacturing and sale of fake drug	1) *Confiscation of unlawful income;* 2) *Suspension of manufacturing and business for correction;* 3) *Revocation of drug approval documents, and/or drug manufacturing license, drug trading license, or medical organization pharmaceutical preparation license*; 4) *Prohibition of application for drug manufacturing license, drug trading*	1) *Confiscation of unlawful income;* 2) *Suspension of manufacturing and business for correction;* 3) *Revocation of drug approval documents, and/or drug manufacturing license, drug trading license, or medical organization pharmaceutical preparation license;* 4) *Fines:* ***more than two but less than five times*** *the value of drug unlawful*

	license, or medical organization pharmaceutical license for ten years; 5) *Prohibition of importation for ten years for foreign MAH;* 6) *Fines:* • ***more than fifteen but less than thirty times** the value of the drugs unlawful manufactured or sold;* • *if the value of the drugs is less than RMB 100,000, it shall be calculated as RMB 100, 000;* • *minimum amount: RMB 1,500,000. (Article 116)*	*manufactured and sold. (Article 73)*
Manufacturing and sale of sub-standard drug	1) *Confiscation of unlawful income;* 2) *Suspension of manufacturing and business for correction;* 3) *Revocation of drug approval documents, and/or drug manufacturing license, drug trading license, or medical organization pharmaceutical preparation license;* 4) *Fines:* • ***more than ten but less than twenty times** the value of the drug unlawfully manufactured and sold;* • *if the value of the drugs unlawful manufactured or wholesaled is less than RMB 100,000, it shall be calculated as RMB 100,000; if the value of the drugs unlawful retailed is less than RMB 10,000, it shall be calculated as RMB 10,000;* • *minimum amount: RMB 100,000. (Article 117)*	1) *Confiscation of unlawful income;* 2) *Suspension of manufacturing and business for correction;* 3) *Revocation of drug approval documents, and/or drug manufacturing license, drug trading license, or medical organization pharmaceutical preparation license;* 4) *Fines: **more than one but less than three times** the value of the drug unlawfully manufactured and sold. (Article 74)*

As for the personal liabilities for the manufacturing and sale of vaccines which are considered as fake drug or sub-standard drug, no financial penalties are set forth by the *Drug Administration Law (Version 2015),* but the *Revised Drug Administration Law* has changed such provision and imposed financial penalties on in charge persons as follows:

Revised Drug Administration Law	***Drug Administration Law (Version 2015)***
• *Confiscation of unlawful income;* • *Prohibition of engaging in the manufacturing and sales of drugs **for life**;* *Fines of **more than 30% but less than three times** of the unlawful income. (Article 118)*	• *Prohibition of engaging in the manufacturing and sales of drug for **ten years**.* *(Article 75)*

Conclusion

The *Revised Drug Administration Law*, as the second comprehensive revision to the *PRC Drug Administration Law*, is a big progress in China on drug administration, and shows the determination of the Chinese government to encourage the drug innovation and protect the interest of the people.

[1] Now named NMPA, National Medical Products Administration.

[2] The ten pilot areas are Beijing, Tianjin, Hebei, Shanghai, Jiangsu, Zhejiang, Fujian, Shandong, Guangdong and Sichuan.

[3] The pilot period set forth by the *Plan* was 3 years, and such period was extended for another 1 year by the *Decision of the Standing Committee of the National People's Congress on Extending the Pilot Period of Authorizing the State Council to Carry out the Pilot Drug Marketing Authorization Holder Regime in Certain Places* dated on 5 November 2018.

[4] According to Article 10 of the *Implementing Regulations*, the blood products shall not be subject to the mandated manufacturing.

[5] No prohibition in the *Administrative Measures of Narcotic Drugs and Psychotropic Drugs* revised and effective as of 6 February 2016.

[6] No prohibition in the *Administrative Measures of Narcotic Drugs and Psychotropic Drugs* revised and effective as of 6 February 2016.

[7] No prohibition in the *Administrative Measures of Toxic Drug for Medical Use* effective as of 27 December 1988.

[8] According to Article 12 of the *Administrative Measures of Pharmaceutical Precursor Chemical* effective as of 1 May 2010, the pharmaceutical precursor chemical shall not be subject to the mandated manufacturing.

[9] According to the *PRC Vaccines Administration Law,* the mandated manufacturing of vaccines can be allowed if the Vaccines MAH can get the relevant approval of the medical products administration under the State Council to such mandated manufacturing.

[10] Good Manufacturing Practice

[11] According to Article 78 of the *Drug Administration Law (version 2015)*, the violation of GMP standard and GSP standard shall be subject to a fine up to RMB 20,000. This is no punishment for the legal representative or main person-in-charge for such violation.

[12] Good Supply Practice

[13] According to Article 126 of the *Revised Drug Administration Law*, in violation of GMP standard or GSP standard, the relevant manufacturing enterprise or drug trading company will be imposed a fine up to RMB 2,000,000. The legal representative, main person-in-charge, direct person-in-charge and other responsible person of the aforesaid enterprise/company shall also be imposed a fine up to 50% of the unlawful income during the violation period, and shall be prohibited from engaging in drug manufacturing and trading activities for a period from ten years to the whole life.

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