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China Insight

Vaccines Administration Law in China

Dear Sir or Madam,

Please find below our update on Vaccines Administration Law in China.

Kind regards,
CMS, China

On 29 June 2019, the Standing Committee of the National People's Congress of the People's Republic of China (the "**PRC**") promulgated the *PRC Vaccines Administration Law* (the "**Vaccines Administration Law**"). The *Vaccines Administration Law* will come into effect on 1 December 2019, i.e. on the same day when the newly revised *PRC Drug Administration Law* promulgated on 26 August 2019 (the "**Revised Drug Administration Law**") will come into effect.

The *Vaccines Administration Law* has altogether eleven chapters, i.e., General Provisions, Vaccine Development and Registration, Vaccine Production and Lot Release, Vaccine Circulation, Vaccination, Monitoring and Handling of Adverse Event to Vaccination, Post-market Management, Safeguard Measures, Supervision and Administration, Legal Liabilities, Supplementary Provisions with in total 100 articles.

Before this *Vaccines Administration Law* is promulgated, the relevant provisions regarding the administration of vaccines are stipulated in the *PRC Drug Administration Law*, the *Prevention and Treatment of Infectious Diseases Law of the PRC*, the *Administrative Regulations on the Circulation of Vaccines and Vaccination of the PRC* and other relevant laws and regulations. According to Article 2 of the *Vaccines Administration Law*, vaccines development, production and circulation, vaccination and supervision and administration within the territory of the PRC shall be subject to this *Vaccines Administration Law.* If there are any issues which are not prescribed in this *Vaccines Administration Law*, the provisions of the *PRC Drug Administration Law*, the *Prevention and Treatment of Infectious Diseases Law of the PRC* and other laws and regulations shall apply. The current regulations of vaccines, especially the *Administration Regulations on the Circulation of Vaccines and Vaccination of the PRC* should be amended to be in line with the *Vaccines Administration Law*.

We summarize its main content and highlights as below:

1 New classification of vaccines

The *Vaccines Administration Law* provides new classification of vaccines.

According to Article 2 of the *Vaccines Administration Law*, vaccines refer to preventive biological products for human vaccination so as to prevent and control the occurrence and prevalence of diseases, including vaccines under immunization programs (the "**Vaccines Under Program**") and vaccines not covered by immunization programs (the "**Vaccines Beyond Program**").

According to Article 97 of the *Vaccines Administration Law*,

- **Vaccines Under Program** refer to the vaccines that shall be inoculated to residents in accordance with

government provisions, including vaccines determined in national immunization programs, vaccines added by people's governments of provinces, autonomous regions and municipalities directly under the Central Government in the implementation of national immunization programs, and vaccines used in emergency vaccination or group preventive vaccination organized by people's governments at the county level or above or their competent health departments, which is similar to the Vaccines of Class 1 under the previous classification under the *Administrative Regulations on the Circulation of Vaccines and Vaccination of the PRC*.

- **Vaccines Beyond Program** refer to other vaccines voluntarily inoculated by residents, which is similar to Vaccines of Class 2 under the previous classification.

The *Vaccines Administration Law* further provides the different administrative rules with regards to the Vaccines Under Program and Vaccines Beyond Program, mainly as follows:

	Vaccines Under Program	***Vaccines Beyond Program***
Purchase of vaccines	***Centralized bidding or unified negotiation*** *organized by the competent health department in conjunction with the public finance department of the State Council.* *(Article 32)*	***Through provincial public resource trading platforms***. *(Article 32)*
Vaccination Institution	*Qualified medical institution designated by local health department at or above the county level.* *(Article 44)*	*Qualified medical institutions and subject to the report and recordal of the competent health department*. *(Article 44)*
Charges of Vaccination Fee	*The inoculation entity* ***shall not charge any fees***. *(Article 49)*	*The inoculation entity may, in addition to charging the* ***vaccine fee****, charge the* ***vaccination service fee***. *(Article 49)*
Compensation Fees for Adverse Event to Vaccination	*The compensation fees shall be allocated from* ***vaccination funds by public finance departments*** *of people's governments of provinces, autonomous regions and municipalities directly under the Central Government.* *(Article 56)*	*The compensation fees shall be* ***assumed by the relevant market authorization holder of vaccine***. *(Article 56)*

Compared with the previous classification which only applies for the circulation and vaccination of vaccines, the new classification can be applied for the whole process of the vaccines, and also be integrated with the series of rules set up/clarified by the *Vaccines Administration Law*.

2 Introduction of definition of market authorization holder regime to vaccines

The *Vaccines Administration Law* introduces the definition of market authorization holder of vaccines (the "**Vaccines MAH**"), which is the first time that MAH regime can be applied for vaccines in China. According to the *Vaccines Administration Law*, the Vaccines MAH shall be responsible for the safety, efficacy, and quality controllability of vaccines.

Back in 2016, the MAH regime was implemented in China as pilot regime in certain areas by the *Circular of the General Office of the State Council on Issuing the Pilot Program for the Drug Market Authorization Holder Regime* (the "**Plan**") dated 26 May 2016. According to the Plan, the market authorization holder of a drug (the "**MAH**") can be either a manufacturing enterprise or a research institution to encourage the innovation and development of drug. Vaccines were excluded from such MAH regime.

According to the *Revised Drug Administration Law*, the MAH regime becomes the national regime. The *Revised Drug Administration Law* specifies that the MAH refers to the manufacturing enterprise or research institution who obtains the drug registration certificate. The *Revised Drug Administration Law* further specifies that the MAH can be a foreign enterprise. Such foreign enterprise shall designate a Chinese enterprise to fulfill the obligations of MAH within the territory of the PRC on behalf of the foreign enterprise. The MAH and such designated Chinese enterprise shall bear joint and several liabilities.

However, according to Article 97 of the *Vaccines Administration Law*, Vaccines MAH refers to the enterprise who obtains both a vaccine registration certificate **and** a drug manufacturing license. This implies that a CRO cannot become a Vaccines MAH and only a manufacturing enterprise can become the Vaccines MAH. In addition, it also implies that the Vaccines MAH should be a Chinese enterprise since only the Chinese enterprise is entitled to hold a drug manufacturing license. Thus, such Vaccines MAH is just a so-called "MAH" but should be different from the MAH regime of drug set forth by the *Revised Drug Administration Law*.

In addition, in the case of the imported vaccines, it is unclear which party should act as the Vaccines MAH. This point should be further clarified.

3 New rules for mandated manufacturing

According to Article 22 of the *Vaccines Administration Law*, the Vaccines MAH shall have the vaccines manufacturing capacity, where the mandated manufacturing is necessary due to inadequate vaccines manufacturing capacity of the Vaccines MAH, it shall obtain the approval of the medical products administration under the State Council to such mandated manufacturing.

Before this *Vaccines Administration Law* comes into force, the mandated manufacturing of vaccines is prohibited according to Article 10 of the *Implementing Regulations of the Drug Administration Law of the PRC* revised and effective as of 2 March 2019. This implementing regulation should be further amended to be in line with the *Vaccines Administration Law* as well as the *Revised Drug Administration Law*.

4 New rules of keeping of sales records

According to Article 39 of the *Vaccines Administration Law*, the Vaccines MAH shall keep accurate and complete sales records and keep the same for reference for at least five years after the shelf life of the relevant vaccines.

Before this *Vaccines Administration Law* comes into force, such period is 2 years according to Article 18 of the *Administrative Regulations on the Circulation of Vaccines and Vaccination of the PRC*.

Compared with the general rules for record keeping of the drugs, the above-mentioned record keeping period for vaccines is longer. According to Article 162 of the *Good Manufacturing Practice for Drugs* (the "**GMP**") revised and effective as of 1 March 2011, the manufacturing enterprise shall keep the sale record of each batch of drugs for at least one year after the shelf life of the relevant drugs.

5 Introduction of new rules of process electronic traceability of vaccines

According to Article 10 of the *Vaccines Administration Law*, the State shall set up national vaccines electronic traceability collaboration platform and the Vaccines MAH shall also establish vaccines electronic traceability system to be linked with the national vaccines electronic traceability collaboration platform, for the purpose of integrating whole process traceability information on vaccine production, circulation and vaccination so as to realize the traceability of vaccines. In case of failure of complying with such obligation, the Vaccines MAH shall be imposed a fine up to RMB 2 million in accordance with Article 83 of the *Vaccines Administration Law.*

Compared with the *Revised Drug Administration Law* which requires the traceability of drugs without specifying the requirements of establishment of electronic system, the *Vaccines Administration Law* provides a more detailed rules to realize the traceability of vaccines.

6 New rules of compulsory vaccines liability insurance

According to Article 68 of the *Vaccines Administration Law*, the State shall implement the rules for compulsory vaccines liability insurance. The Vaccines MAH shall underwrite the compulsory vaccine liability insurance. Specific implementing measures for the compulsory vaccine liability insurance system shall be formulated by the medical products administration under the State Council in collaboration with the health administration and insurance regulatory authority under the State Council, etc. In case of failure of complying with such obligation, the Vaccines MAH shall be imposed a fine up to RMB 2 million in accordance with Article 83 of the *Vaccines Administration Law.*

7 New rules of post-market management of vaccines

a) Post-market investigation by Vaccines MAH

According to the *Vaccines Administration Law*, the Vaccines MAH shall establish the whole-lifecycle quality management system of vaccines, and carry out post-market investigation to further confirm the safety, efficacy and quality controllability of the vaccines put into the market. In case of failure of complying with

such obligation, the Vaccines MAH shall be imposed a fine up to RMB 2 million in accordance with Article 83 of the *Vaccines Administration Law*.

b) Quality retrospection analysis and risk reporting by Vaccines MAH

According to Article 60 of the *Vaccines Administration Law*, the Vaccines MAH shall set up a vaccines quality retrospection analysis and risk reporting system, and faithfully report relevant information on vaccine manufacturing, distribution, post-market investigation and risk management and etc., to the medical products administration under the State Council on a yearly basis. In case of failure of complying with such obligation, the Vaccines MAH shall be imposed a fine up to RMB 2 million in accordance with Article 83 of the *Vaccines Administration Law*.

c) Post-market evaluation

According to Article 61 of the *Vaccines Administration Law*, the medical products administration under the State Council has the right to request a Vaccines MAH to conduct post-market evaluation or directly organize post-market evaluation. The medical products administration under the State Council shall cancel the drug registration certificate for vaccines with serious adverse event to vaccination or endangering human health due to other causes.

8 New rules of obligation to disclose information by Vaccines MAH

According to Article 74 of *Vaccines Administration Law*, the Vaccines MAH shall establish an information disclosure system and promptly disclose vaccine product information, package insert and labels, situations concerning the implementation of the Good Manufacturing Practice, lot release, recall, inspection and punishment imposed and compulsory vaccine liability insurance effected, etc. on its website as required. In case of failure of complying with such obligation, the Vaccines MAH shall be imposed a fine up to RMB 2 million in accordance with Article 83 of the *Vaccines Administration Law.*

9 Severe administrative punishment

The *Revised Drug Administration Law* sets forth the strict administrative penalties regarding the violation of the *Revised Drug Administration Law*. The administrative penalties regarding the violation of the *Vaccines Administration Law* are even stricter. We compare below the administrative penalties to be imposed for the manufacturing and sales of fake drug[1] and sub-standard drug[2] in the *Revised Drug Administration Law* and the *Vaccines Administration Law.*

	Revised Drug Administration Law	***Vaccines Administration Law***

Manufacturing and sale of fake drug	• *Confiscation of unlawful income;*
	• *Suspension of manufacturing and business for correction;*
	• *Revocation of drug approval documents, and/or drug manufacturing license, drug trading license, or medical organization pharmaceutical preparation license;*
	• *Prohibition of application for drug manufacturing license, drug trading license, or medical organization pharmaceutical license for ten years;*
	• *Prohibition of importation for ten years for foreign MAH;*
	• *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)*
		• *Confiscate of unlawful income;*
		• *Suspension of manufacturing and business for correction;*
		• *Revocation of drug registration certificate and/or drug manufacturing license and etc.;*
		• *Fines:*
		  • ***more than fifteen times but less than fifty times*** *the value of the vaccines unlawful manufactured or sold;*
		  • *if the value is less than RMB 500,000, it shall be calculated as RMB 500,000;*
		  • *minimum amount: RMB 7,500,000. (Article 80)*

Manufacturing and sale of sub-standard	• *Confiscation of unlawful income;* • *Suspension of manufacturing and business for correction;*	• *Confiscation of unlawful income;* • *Suspension of manufacturing and business for correction;*

drug	• *Revocation of drug approval documents, and/or drug manufacturing license, drug trading license, or medical organization pharmaceutical preparation license;*
	• *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)*
		• *Revocation of drug registration certificate and/or drug manufacturing license and etc.;*
		• *Fines:*
		  • ***more than ten times but less than thirty times*** *the value of vaccines unlawfully manufactured and sold;*
		  • *if the value is less than RMB 500,000, it shall be calculated as RMB 500,000;*
		  • *minimum amount: RMB 5,000,000. (Article 80)*

As for the personal liabilities for the manufacturing and sale of vaccine which is considered as fake drug or sub-standard drug, no financial penalties are set forth by the *Drug Administration Law* effective as of 24 April 2015 (the "**Drug Administration Law (Version 2015)**") but the Revised *Drug Administration Law* has changed such provision and imposed financial penalties on in charge persons. Such financial penalties are also added into the *Vaccines Administration Law* and the amount of penalties is even higher.

Drug Administration Law (Version 2015)	***Revised Drug Administration Law***	***Vaccines Administration Law***
• *Prohibition of engaging in the manufacturing and sales of drug for* ***ten years****. (Article 75)*	• *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)*	• *Confiscation of unlawful income;* • *Prohibition of engaging in the manufacturing and sales of drugs* ***for life****;* • *Fines of* ***more than one time but less than ten times*** *the unlawful income;* • *Administrative detention. (Article 80)*

Conclusion

The *Vaccines Administration Law* implements the most stringent management rules for vaccines, and adhere to safety first, risk management, whole-process management and control, scientific, supervision, and social co-governance. This *Vaccines Administration Law* is considered as the "strictest" management of vaccine in China which provides the strongest protection to the human safety and the severest punishment for the illegal acts relating to vaccines in China. Such new law shows the determination of the Central Government of fighting against the chaos in the vaccine industry and the effort to protect the interest of the people.

[1] **Fake drug** refers to the following drugs: the ingredients in the drug are different from those specified by the national drug standards; a non-drug substance is simulated as a drug or one drug is simulated as another; degenerated drug; or the indication or duction indicated are beyond the specified scope.

[2] **Sub-standard drug** refers to the following drugs: the quantity of the ingredients in the drug are different from these specified by the national drug standards; polluted drug; drug without expiration date or such date being changed; drug without approval number or such number being changed; drug beyond the expiration date; drug with unapproved preservative or ingredients.

In case you have questions or for further information, please contact the authors of this newsletter:

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