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New Systems under the Vaccine Administration Law

By Xun Yang | Nora Wu

In recent years, quality and safety of vaccines products have becoming public concerns. Especially, Changchun Changsheng Life Sciences Ltd. was found to have falsified records in the process of manufacturing rabies vaccine for humans, which raised widespread public concerns. Under the circumstances, on Nov 11, 2018, the State Administration for Market Regulation promulgated the draft Vaccine Administration Law of the People's Republic of China ("Vaccine Administration Law") and the drafting notes, aiming to strengthen the regulation on the development, manufacture, distribution, application, adverse reaction monitoring, safeguard, supervision of vaccine products.

The drafting of Vaccine Administration law closely follows the amendment to the Pharmaceutical Administration Law and take as reference some institutional arrangements under the amendment, including without limitations, establishing a Marketing Authorization Holder System ("MAH system") to enhance the supervision on drug clinical research and increase the penalties for the drug safety violations. Nevertheless, the Vaccine Administration Law differs from the Pharmaceutical Administration Law and has stricter rules.

The new systems stipulated in the Vaccine Administration Law are listed as follows:

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I. Marketing Authorization Holder System of Vaccine

The Vaccine Administration Law establishes the Marketing Authorization Holder System of Vaccine ("MAH system for vaccine"), which is largely in line with the MAH system stipulated under the amendment to Pharmaceutical Administration Law. Even though both of them could, in certain degree, strengthen the safety responsibility for drugs and vaccines, there are some differences between them.

Both pharmaceutical manufacturers and R&D institutions without drug manufacturing license can act as marketing authorization holders ("MAHs"), which is definitely a reformation from the past administration mode under which market authorizations for drugs and manufacturing permissions are combined. The pharmaceutical manufacturing permission is no longer a prerequisite for being a MAH, of which the main purpose is to fully mobilize drug developers, to promote innovation in drug development, to clarify the liabilities of producers, operators and regulators, and to optimize the allocation of resources. Additionally, the establishment of MAH system will facilitate the transfer of market authorization for drugs.

The MAH system for vaccine is different in that, MAHs of vaccines must be vaccine manufacturers. Only qualified manufacturers for vaccines holding approvals from the drug regulator is allowed to apply for and hold market authorization for vaccines. MAHs of vaccines are required to be responsible for the safety, efficiency and quality of the development, manufacture and distribution of vaccine.

As such, the purpose to establish a MAH system for vaccine is not for the separation of the vaccine R&D and manufacture, but for strengthening the safety responsibility. Vaccine is a special type of drug and, because of its biological activity, the transportation and storage requires some special treatment, such as to maintain a specific low temperature to prevent the vaccine from being inactive. For the purpose of avoiding difficulties in allocating responsibilities between manufacturers, transporters and distributors, MAHs of vaccines is required to bear primary responsibility for the safety, effectiveness and quality of vaccine throughout the development, manufacture and distribution.

Furthermore, in order to ensure the safety and reliability of vaccine manufacture and operation, the MAH system for vaccine also includes the following requirements:

(1) Only MAHs of vaccines are entitled to engage in the manufacture of the licensed vaccine, and commissioned manufacturing to a third party to produce vaccines is prohibited, which are different from drug manufacture.

(2) Personnel subject to restrictions on access to relevant industries are forbidden from engaging in vaccine manufacturing activities. MAHs of vaccines must conduct background check against potential candidates before reciting them to key positions and the items to be checked include credit records, professional backgrounds and relevant experience. Any change in key positions must be reported by the MAHs of vaccines to the regulator at the provincial level.

(3) MAHs of vaccines must establish and improve its managerial system for vaccine quality and report to the competent authority of any change in in manufacturing technique, location and critical equipment.

(4) If the manufacturing technique or quality control is obviously below the standards of other vaccines of the same kind and cannot satisfy the requirements within the time limit prescribed by the regulator, the MAHs of vaccines must proactively apply for the cancellation of the marketing authorization.

(5) MAHs of vaccines must subscribe liability insurance, by which insurance company will compensate the victims within coverage if a quality issue associated with vaccines occurs.

II. Digital Whole-Process Tracing System for Vaccines

The Vaccine Administration Law aims to establish a Digital Whole-Process Tracing System for Vaccines (the "Tracing System"). At the government level, the drug regulator is supposed to work together with the National Health Commission to enact unified standards and regulations on the vaccine tracing, and set up a national electronic traceability collaboration platform to trace the whole process, including the manufacture, distribution and application of vaccines, so that the vaccine quality and safety can be monitored.

At the company level, MAHs of vaccines are required to establish a Tracing System to achieve the traceability and verifiability of vaccine at its smallest unit in the whole process, including the manufacture, storage, transportation and application. Institutions for disease prevention and control as well as clinics which apply vaccines must, in accordance with the laws, truthfully record the vaccine distribution, use and other situations, and provide the tracing information at the required standards. They are required to retain relevant records or supporting documents for at least five (5) years after the expiration of the validity period of the vaccines. It is worth noting that, the retention period stipulated in the current-effective Regulations on the Administration of Circulation and Vaccination of Vaccine ("Regulations") is only two (2) years. Therefore, such retention period will be significantly extended once the Vaccine Administration Law is adopted in its current form.

It is also worthy noting that, the government intends to establish the unified Tracing System, which means vaccine manufacturing, transporting and distributing must select and use information network terminal at a stipulated technical standard, with modules satisfying certain functional requirements, and using compatible data interfaces. This gives rises to certain requirements on the information systems and IT operations management of vaccine companies.

Meanwhile, the operator of the Tracing System will have access to all data generated by vaccine manufacturers and distributors as processed in their systems. Therefore, the reliability of the system and its operation, as well as the freedom of selection must be taken into consideration. From the perspective of the Tracing System, it must achieve the compatibility between data transmitted from each terminals and, at the same time, vaccine manufacturers and distributors must have freedom to choose the information systems as far as certain technical specifications are met. From the perspective of system operators, the operators must have safety operating capability and, at the same time, they must be neutral, which means, they must not engage in a business of vaccine manufacturing or distribution to avoid misuse their accesses to the data generated by vaccine manufacturers and distributors.

III. Uniform system for Publicizing Vaccine Safety Information

Considering the public panic resulting from recent vaccine safety accidents, the Vaccine Administration Law proposes to establish a uniform system for publicizing vaccine safety information (Publicizing System), which includes:

From the government aspect, as stipulated in the Vaccine Administration Law, the drug regulator, in conjunction with relevant government agencies, disclose vaccine alerts on vaccine safety, major vaccine safety accidents and their investigation status. The report on adverse reaction to vaccination must be exclusively published by the National Health Commission. Any person or entity without authorization must not publish the aforementioned information. The drug regulator must work together with the department of public health or other government agencies, professional institutions and the MAHs of vaccines concerned, to verify and analyze the information which may confuse the public and mislead the public opinions, and promptly announce the results thereof.

From the aspects of MAHs of vaccines, they must establish Publicizing System and timely disclose on its website product information, specifications and labels, implementation of quality control, and information concerning lot releases, product recalls and insurance. Serious adverse reaction must be reported to the competent authority without delay, which requires MAHs of vaccines to trace the distribution and application of vaccines, including the effect and adverse reaction after vaccinations. In addition, MAHs of

vaccines are required to establish and strengthen the systems for collecting and protecting personal information, and obtain the consents of data subjects where the collection, processing, reporting and disclosure of their personal effects and adverse reactions are involved.

IV. Suggestions

The administration and control on the manufacture and operation of vaccine will be greatly strengthened once the Vaccine Administration Law is adopted in its current form. In particular, with regard to the vaccine manufacturers:

(1) The establishment of MAH system for vaccine requires licensed vaccine manufacturers to ensure the safety and reliability of vaccines, and to take control over the distribution of vaccines. In particular, MAHs of vaccine must conduct due diligence against the qualifications and abilities of its distributors, and enter into agreements with them for quality control.

(2) MAHs of vaccines must enhance the construction of information system and improve the management of information, including the procurement, establishment and operation of the information system which complies with the regulatory requirements, and adopt legitimate and reasonable methods and means to collect information required to be filed and reported, so as to achieve the balance between accurate tracing of vaccine distribution, utilization, effects and adverse reactions, and personal privacy.

The Vaccine Administration Law imposes higher requirements on the vaccine manufacturers and distributors and increases their operating costs. However, it can may help to exclude the enterprises with poor qualifications and capabilities out of the market, and create a favorable market environment. In other words, this could be a good news for decent vaccine manufacturers and distributors.

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