

Client Alert

NOVEMBER 2019

A new law for vaccine manufacturers supplying vaccines to China

After a troubled couple of years in relation to the quality and standards of vaccines, particularly those meant for children, the national legislative body of the People's Republic of China, the National People's Congress, adopted and announced The Vaccines Administration Law ("the Law") on June 29, 2019. It comes into effect on December 1, 2019.

What does the law do and change?

In an effort to combat the recent chaos in the vaccine industry and to protect the interest of the population the Law implements stringent management rules for vaccine quality, and incorporates strong protections for human safety.



It requires the "vaccine marketing authorization holder" to be responsible for the safety, effectiveness and good product quality of a vaccine throughout the whole lifecycle of the licensed product, that is, the entire process from vaccine development, production and distribution, through to and including vaccinations themselves.

This is a major change. Prior to this law, risk management of vaccines in China relied on the supervision of the regulatory authorities, with vaccine companies playing a relative passive role throughout the chain. These changes mean the main responsibility for risk management is transferred from the governmental regulatory bodies to vaccine companies.

The Law also contains severe punishment for breaches. Importantly, it contains some compulsory liability insurance provisions.

To who and what does the law apply?

Back in 2005 a central government regulation on vaccine distribution and vaccination divided the country's approved vaccines into two categories:

1. **Compulsory Vaccines** – vaccines all residents are required to take – free of charge.
2. **Voluntary Vaccines** – vaccines residents may choose whether or not to take – and for which there will be a charge.

Manufacturers or vaccine marketing authorization holders of both compulsory and voluntary vaccines must purchase liability insurance covering bodily injury arising out of vaccine hazards/defects (clause 68 of the Law). In addition, purchase of commercial insurance by vaccine enterprises is encouraged, to cover any side effects of vaccinations which are not necessary linked with vaccine defects.

How this insurance is acquired, is likely to be different for compulsory to voluntary vaccines, and in different provinces. For example, it's possible that an authority in one province may arrange centralized insurance programs for compulsory vaccine companies but not for voluntary vaccine companies. Such an arrangement may not be offered by other provinces. There are no definitive conclusions around this, as yet.

Implications

If your company supplies compulsory vaccines, you need to be speaking with the authorities in each province in which you sell, to understand what, if any, centralized insurance will be arranged. Then you need to make an assessment as to whether this is sufficient coverage for your exposures under the new law.

If your company supplies voluntary vaccines, you are likely to need your own insurances to cover your exposures under this law.

If you need assistance, please contact:

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Outstanding information

Although the new law will be come into effect on December 1st 2019:

- compulsory minimum insurance policy limits are yet to be announced.
- detailed insurance regulatory requirements are still unavailable.

How Marsh can help?

We are monitoring the situation and the legal developments.

We have a firm view as to the insurances manufactures/ marketing authorization holders should purchase, and how to calculate the limits they should buy in order to protect both themselves and the users of their products in China.

We have provided advice and solutions to Life Sciences clients in China and believe we are best placed to provide a right-sized solution, depending upon your geographic reach and exposures under this new law. We look forward to being able to help you navigate these changes so your business can continue to thrive.