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China: Vaccine Law Passed

(Aug. 27, 2019) On June 29, 2019, the National People's Congress Standing Committee of the People's Republic of China (PRC or China) adopted the [PRC Law on Vaccine Administration](#) (Vaccine Law). The official Xinhua news agency [states](#) that the Law provides for the "strictest" vaccine management with tough penalties in order to ensure the country's vaccine safety.

Before the passage of this 100-article Law, provisions governing vaccines [were contained](#) in the PRC Drug Administration Law, PRC Law on the Prevention and Treatment of Infectious Diseases, and a few relevant administrative regulations and rules.

The new Law provides for regulatory requirements for researching, producing, distributing, and using vaccines. Such requirements, according to one legal commentator, are [much more stringent](#) than those for other drugs (art. 2). It also contains a chapter specifying penalties for violating the Vaccine Law, which are also stricter than those for violating other drug laws (ch. 10). According to the Law, if any violation of this Law constitutes a crime, a "heavier punishment" within the range of punishments provided by the Criminal Law on the relevant crimes is to be imposed (art. 79).

The Law mandates the launching of a national vaccine electronic tracking platform that integrates tracking information throughout the whole process of vaccine production, distribution, and use to ensure all vaccine products can be tracked and verified (art. 10).

According to the Law, China is to implement a state immunization program, and residents living within the territory of China are legally obligated to be vaccinated with immunization program vaccines, which are provided by the government free of charge. Local governments and parents or other guardians of children must ensure that children be vaccinated with the immunization program vaccines (art. 6).

The Law establishes a compensation system for abnormal reactions to vaccination. A recipient of an immunization program vaccine who dies or suffers significant disability or organ and tissue damage is to be paid from the vaccination funds of the provincial level government if the damage falls within the scope of abnormal reactions associated with a vaccine or cannot be prevented (art. 56).

The Law will take effect on December 1, 2019 (art. 100).

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