Vaccine Administration Law of the People’s Republic of China

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Chapter I — General Provisions

Article 1 — This Law is enacted for the purposes of strengthening vaccine administration, ensuring vaccine quality and supply, regulating vaccination, promoting the development of the vaccine industry, safeguarding public health, and maintaining public health security.

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Article 2 — This Law shall apply to vaccine research and development, manufacturing, distribution, vaccination, and supervision and administration activities within the territory of the People's Republic of China. For purposes of this Law, vaccines are pharmaceutical products used for human immunization to prevent and control the occurrence and spread of diseases.

Article 3 — Vaccine administration shall adhere to the principles of being people-centered, prioritizing safety, implementing the strictest supervision, and ensuring the safety, effectiveness, and accessibility of vaccines.

Article 4 — The state shall implement a national immunization program. Vaccines in the national immunization program shall be provided free of charge to recipients.

Article 5 — The drug regulatory department under the State Council shall be responsible for nationwide vaccine supervision and administration. The health administrative department under the State Council shall be responsible for nationwide vaccination supervision and administration.

Article 6 — The state shall support basic and applied research on vaccines, encourage vaccine innovation, and promote the development and industrialization of new vaccines.

Chapter II — Vaccine Research and Development

Article 7 — Vaccine research and development institutions shall possess the necessary personnel, facilities, equipment, and management systems, and shall comply with Good Laboratory Practice (GLP) for non-clinical studies and Good Clinical Practice (GCP) for clinical trials.

Article 8 — Vaccine clinical trials shall be conducted in three phases: Phase I (preliminary safety and immunogenicity), Phase II (dose-ranging and preliminary efficacy), and Phase III (large-scale efficacy and safety). The protocols must be approved by the drug regulatory department.

Article 9 — Vaccine clinical trials shall be conducted at qualified clinical trial institutions. An ethics review committee shall evaluate and approve the trial protocol before commencement.

Article 10 — Informed consent shall be obtained from trial subjects or their legal guardians before participation. Subjects shall be fully informed of the purpose, methods, risks, and potential benefits of the trial.

Article 11 — The state shall establish a system of urgent authorization for vaccines needed in public health emergencies, permitting accelerated review and approval under specific conditions.

Chapter III — Vaccine Manufacturing and Batch Release

Article 12 — Vaccine manufacturing shall be subject to a manufacturing license system. Vaccine manufacturers shall obtain a Drug Manufacturing License and a Good Manufacturing Practice (GMP) certificate from the drug regulatory department.

Article 13 — Vaccine manufacturers shall establish sound quality management systems covering all stages from raw material procurement through finished product distribution.

Article 14 — The state shall implement a batch release system for vaccines. Each batch of vaccine shall undergo testing or review by the designated batch release institution before it may be marketed or distributed.

Article 15 — Vaccine manufacturers shall establish an electronic traceability system that records the entire lifecycle, from manufacturing through distribution to vaccination, ensuring traceability of each unit of vaccine.

Article 16 — The state shall implement a vaccine lot-based electronic record system. The relevant information shall be disclosed to the public through a national vaccine lot-based information platform.

Chapter IV — Vaccine Distribution

Article 17 — Vaccine distribution shall be subject to a licensing system. Distributors shall obtain the appropriate business license from the drug regulatory department.

Article 18 — Vaccines shall be stored and transported under cold-chain conditions in accordance with prescribed temperatures and procedures. Temperature monitoring devices shall be used throughout the cold chain.

Article 19 — Vaccine manufacturers shall distribute vaccines in accordance with the procurement contracts concluded with disease prevention and control institutions.

Article 20 — Disease prevention and control institutions at all levels shall distribute vaccines to vaccination units in accordance with state provisions, ensuring vaccine quality during transit.

Chapter V — Vaccination

Article 21 — Vaccination units shall meet prescribed conditions, including qualified medical personnel, adequate vaccination rooms, cold-chain equipment, and emergency treatment facilities.

Article 22 — Prior to vaccination, vaccination personnel shall inform recipients or their guardians of the vaccine variety, function, contraindications, adverse reactions, and precautions, and shall obtain informed consent.

Article 23 — Vaccination personnel shall verify recipient information, check the vaccine variety, dosage form, dosage, and expiration date, and strictly follow standard operating procedures.

Article 24 — Recipients shall be observed for at least 30 minutes after vaccination at the vaccination site. Vaccination units shall be equipped to handle acute adverse reactions.

Article 25 — Vaccination records shall be truthfully recorded, including the vaccine variety, manufacturer, batch number, date of vaccination, vaccination personnel, and recipient information. Records shall be preserved for the prescribed period.

Chapter VI — Adverse Reaction Monitoring and Handling

Article 26 — The state shall establish a vaccine adverse reaction monitoring and reporting system. Adverse reactions following immunization shall be promptly reported, investigated, diagnosed, and handled.

Article 27 — Disease prevention and control institutions and vaccination units shall monitor adverse reactions following immunization and report any suspected abnormal reactions to the relevant authorities.

Article 28 — Where an adverse reaction is confirmed to be causally related to vaccination, the recipient shall receive appropriate compensation in accordance with state provisions.

Article 29 — The state shall establish a vaccine injury compensation system funded by the government, with contributions from vaccine manufacturers as appropriate.

Chapter VII — Post-Marketing Management

Article 30 — Vaccine manufacturers shall conduct post-marketing studies, continuously monitoring the safety and effectiveness of their vaccines and reporting to the drug regulatory department.

Article 31 — The drug regulatory department shall conduct regular inspections of vaccine manufacturers and may conduct unannounced inspections at any time.

Article 32 — Where quality defects or safety risks are identified in marketed vaccines, the manufacturer shall initiate a recall. The drug regulatory department may also order a recall.

Article 33 — The state shall establish a vaccine elimination mechanism. Vaccines with serious safety risks or insufficient effectiveness shall be eliminated from the market.

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Chapter VIII — Supervision and Administration

Article 34 — Drug regulatory departments, health administrative departments, and other relevant authorities shall strengthen supervision and inspection of vaccine research, manufacturing, distribution, and vaccination in accordance with their respective responsibilities.

Article 35 — The drug regulatory department shall establish a credit record system for vaccine manufacturers and distributors, and shall publicly disclose information on violations of law.

Article 36 — Any entity or individual shall have the right to report violations of vaccine administration. Relevant authorities shall protect the legitimate rights and interests of whistleblowers.

Chapter IX — Legal Liability

Article 37 — Where a vaccine is manufactured or distributed without a license, the illegal income and the illegally manufactured or distributed vaccines shall be confiscated, and a fine of not less than 15 times but not more than 30 times the value of the vaccines involved shall be imposed.

Article 38 — Where counterfeit vaccines are manufactured or distributed, the illegal income and counterfeit vaccines, raw materials, packaging materials, and manufacturing equipment shall be confiscated, and a fine of not less than 15 times but not more than 50 times the value of the goods shall be imposed.

Article 39 — Where a vaccine manufacturer violates GMP requirements, it shall be ordered to suspend production for rectification. Where the circumstances are serious, the Drug Manufacturing License shall be revoked.

Article 40 — Where any disease prevention and control institution, vaccination unit, or vaccine distributor violates vaccine storage or transportation requirements, it shall be ordered to rectify and may be fined.

Article 41 — Where government officials responsible for vaccine supervision and administration abuse their authority, neglect their duties, or engage in malpractice for personal gain, they shall be subject to disciplinary sanctions; where a crime is constituted, criminal liability shall be pursued.

Article 42 — Where a violation of this Law causes personal injury or property damage to others, civil liability shall be borne in accordance with law.

Chapter X — Supplementary Provisions

Article 43 — The administration of veterinary vaccines shall be governed by separate provisions.

Article 44 — This Law shall come into effect on December 1, 2019.

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