Regulation on the Administration of Circulation and Vaccination of Vaccines (2016 Revision) [Expired]

疫苗流通和预防接种管理条例(2016修订) [失效]

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Regulation on the Administration of Circulation and Vaccination of Vaccines

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疫苗流通和预防接种管理条例

（2005年3月24日中华人民共和国国务院令第434号公布 根据2016年4月23日国务院令第668号《国务院关于修改〈疫苗流通和预防接种管理条例〉的决定》修订）

Chapter I General Provisions

第一章 总 则

Article 1 This Regulation is formulated in accordance with the Pharmaceutical Administration Law of the People's Republic of China (hereinafter referred to as Pharmaceutical Administration Law) and the Law of the People's Republic of China on Prevention and Treatment of Infectious Diseases (hereinafter referred to as the Law on Prevention and Treatment of Infectious Diseases) so as to strengthen the administration of circulation and vaccination of vaccines, prevent and control the occurrence and spread of infectious diseases, and guarantee human health and public sanitation.

第一条 为了加强对疫苗流通和预防接种的管理，预防、控制传染病的发生、流行，保障人体健康和公共卫生，根据《中华人民共和国药品管理法》（以下简称药品管理法）和《中华人民共和国传染病防治法》（以下简称传染病防治法），制定本条例。

Article 2 Vaccines mentioned in this Regulation shall mean the preventive biotic products of the vaccine type, which are used for human vaccination for the sake of preventing and controlling the occurrence and spread of infectious diseases.

Vaccines are divided into two classes. Vaccines of Class 1 shall mean the vaccines provided by the government to citizens free of charge, which shall be vaccinated to citizens in accordance with the government provisions. Vaccines of this class include the vaccines determined in the State's immunity planning, the vaccines added by the people's governments of provinces, autonomous regions, and municipalities directly under the Central Government in the implementation of the State's immunity planning, and the vaccines used in the emergent inoculation or mass vaccination organized by the people's governments at the county level or above or their respective competent health departments. Vaccines of Class 2 shall mean other vaccines with which the citizens are voluntarily inoculated at their own expenses.

第二条 本条例所称疫苗，是指为了预防、控制传染病的发生、流行，用于人体预防接种的疫苗类预防性生物制品。

疫苗分为两类。第一类疫苗，是指政府免费向公民提供，公民应当依照政府的规定受种的疫苗，包括国家免疫规划确定的疫苗，省、自治区、直辖市人民政府在执行国家免疫规划时增加的疫苗，以及县级以上人民政府或者其卫生主管部门组织的应急接种或者群体性预防接种所使用的疫苗；第二类疫苗，是指由公民自费并且自愿受种的其他疫苗。

Article 3 The expenses for inoculation with vaccines of Class 1 shall be borne by the government, while the expenses for inoculation with vaccines of Class 2 shall be borne by the

第三条 接种第一类疫苗由政府承担费用。接种第二类疫苗由受种者或者其监护人承担费用。

inoculated persons or their respective guardians.

Article 4 The circulation and vaccination of vaccines and the supervision and administration thereof shall be governed by this Regulation.

第四条 疫苗的流通、预防接种及其监督管理适用本条例。

Article 5 The competent department of health under the State Council shall, in light of such factors as the spread of infectious diseases within China, the crowd's immunity conditions, etc., formulate the State's immunity planning; and shall, jointly with the department of public finance under the State Council, draft vaccine varieties which are included into the State's immunity planning, and promulgate them upon approval of the State Council.
The people's government of the province, autonomous region, or municipality directly under the Central Government may, when implementing the State's immunity planning, increase the vaccine varieties supplied to citizens free of charge in light of such factors as the spread of infectious diseases, the crowd's immunity conditions, etc. within its own administrative region, and report to the competent department of health under the State Council for archival purposes.

第五条 国务院卫生主管部门根据全国范围内的传染病流行情况、人群免疫状况等因素，制定国家免疫规划；会同国务院财政部门拟订纳入国家免疫规划的疫苗种类，报国务院批准后公布。
省、自治区、直辖市人民政府在执行国家免疫规划时，根据本行政区域的传染病流行情况、人群免疫状况等因素，可以增加免费向公民提供的疫苗种类，并报国务院卫生主管部门备案。

Article 6 The State applies a planned vaccination system, carries out and enlarges the immunity planning.
Those who need to be inoculated with vaccines of Class 1 shall be inoculated in accordance with this Regulation. If the inoculated person is a minor, his guardian shall cooperate with the relevant disease prevention and control institution, medical institution, or other medical and health institution, so as to guarantee the said minor to be inoculated in time.

第六条 国家实行有计划的预防接种制度，推行扩大免疫规划。
需要接种第一类疫苗的受种者应当依照本条例规定受种；受种者为未成年人的，其监护人应当配合有关的疾病预防控制机构和医疗机构等医疗卫生机构，保证受种者及时受种。

Article 7 The responsibility to supervise and administer the vaccination throughout the country shall remain with the competent department of health under the State Council. The competent health department of the local people's government at the county level or above shall be responsible for supervising and administering the vaccination within its own administrative region.
The responsibility to supervise and administer the quality and circulation of vaccines throughout the country shall remain with the drug administration department under the State Council. The drug administration department of the people's government of the province, autonomous region, or municipality directly under the Central Government shall be responsible for supervising and administering the quality and circulation of vaccines within its own administrative region.

第七条 国务院卫生主管部门负责全国预防接种的监督管理工作。县级以上地方人民政府卫生主管部门负责本行政区域内预防接种的监督管理工作。
国务院药品监督管理部门负责全国疫苗的质量和流通的监督管理工作。省、自治区、直辖市人民政府药品监督管理部门负责本行政区域内疫苗的质量和流通的监督管理工作。

Article 8 The medical and health institution designated by the competent health department of a people's government at the county level in accordance with this Regulation (hereinafter referred to as the inoculation entity) shall undertake the vaccination work. The competent health department of the people's government at the county level shall, when designating an inoculation entity, clarify the area of its responsibilities.
The people's government at the county level or above shall reward the inoculation entities and their personnel who undertake vaccination work and have made prominent achievements and contributions.

第八条 经县级人民政府卫生主管部门依照本条例规定指定的医疗卫生机构（以下称接种单位），承担预防接种工作。县级人民政府卫生主管部门指定接种单位时，应当明确其责任区域。
县级以上人民政府应当对承担预防接种工作并作出显著成绩和贡献的接种单位及其工作人员给予奖励。

Article 9 The State supports and encourages entities and individuals to participate in vaccination. The people's government at each level shall improve relevant systems so as to facilitate the entities and individuals to take part in the activities of vaccination work including propaganda, education and donation, etc.
Residents' committees and villagers' committees shall cooperate with relevant departments in carrying out the propaganda and education relating to vaccination, and assist in organizing residents and villagers to be inoculated with vaccines of Class 1.

第九条 国家支持、鼓励单位和个人参与预防接种工作。各级人民政府应当完善有关制度，方便单位和个人参与预防接种工作的宣传、教育和捐赠等活动。
居民委员会、村民委员会应当配合有关部门开展与预防接种有关的宣传、教育工作，并协助组织居民、村民受种第一类疫苗。

Chapter II Circulation of Vaccines

第二章 疫苗流通

Article 10 Vaccines shall be purchased through provincial public resource trading platforms.

第十条 采购疫苗，应当通过省级公共资源交易平台进行。

Article 11 The disease prevention and control institution at the provincial level shall, in light of the State's immunity planning and the needs in preventing and controlling the occurrence and spread of infectious diseases in the local area, make the plan on use of vaccines of Class 1 in the local area (hereinafter referred to as use plan), and report it to the department responsible for procuring vaccines of Class 1 in accordance with the relevant provisions of the State, and meanwhile report it to the competent health department of the people's government at the same level for archival purposes. The use plan shall include such contents as the varieties and quantity of the vaccines, the avenue and method of supply, etc.

第十一条 省级疾病预防控制机构应当根据国家免疫规划和本地区预防、控制传染病的发生、流行的需要，制定本地区第一类疫苗的使用计划（以下称使用计划），并向依照国家有关规定负责采购第一类疫苗的部门报告，同时报同级人民政府卫生主管部门备案。使用计划应当包括疫苗的品种、数量、供应渠道与供应方式等内容。

Article 12 The department responsible for procuring vaccines of Class 1 in accordance with the relevant provisions of the State shall conclude a government procurement contract with a vaccine production enterprise in accordance with law, stipulating the varieties, quantity and prices, etc. of the vaccines.

第十二条 依照国家有关规定负责采购第一类疫苗的部门应当依法与疫苗生产企业签订政府采购合同，约定疫苗的品种、数量、价格等内容。

Article 13 A vaccine production enterprise shall, according to the stipulations in the government procurement contract, supply vaccines of Class 1 to the disease prevention and control institutions at the provincial level or other disease prevention and control institutions designated by the aforementioned institutions, and shall not supply vaccines of Class 1 to any other entities or individuals.

The vaccine production enterprise shall mark the words of "Free of Charge" and the special mark of "Immunity Planning" set forth by the competent department of health under the State Council at an eye-catching position of the smallest exterior packing of the vaccines included into the State's immunity planning which it supplies. The specific administrative measures shall be formulated by the drug administration department under the State Council jointly with the competent department of health under the State Council.

第十三条 疫苗生产企业应当按照政府采购合同的约定，向省级疾病预防控制机构或者其指定的其他疾病预防控制机构供应第一类疫苗，不得向其他单位或者个人供应。

疫苗生产企业应当在其供应的纳入国家免疫规划疫苗的最小外包装的显著位置，标明"免费"字样以及国务院卫生主管部门规定的"免疫规划"专用标识。具体管理办法由国务院药品监督管理部门会同国务院卫生主管部门制定。

Article 14 A disease prevention and control institution at the provincial level shall do a good job in organizing the distribution of vaccines of Class 1, and shall organize the distribution of vaccines of Class 1 to the disease prevention and control institutions at the level of city divided into districts or at the county level according to the use plan. Each disease prevention and control institution at the county level shall distribute the vaccines of Class 1 to the inoculation entities and the medical and health institutions at the township level according to the use plan. Each medical and health institution at the township level shall distribute the vaccines of Class 1 to the village medical and health institutions undertaking the vaccination work. No medical and health institution shall distribute vaccines of Class 1 to any other entity or individual. An institution that distributes vaccines of Class 1 may not charge any fee.

Where, when an infectious disease breaks out or spreads, the local people's government at the county level or above or its competent health department needs to take emergent inoculation measures, the disease prevention and control institution at the level of city divided into districts or above may distribute vaccines of Class 1 directly to the inoculation entities.

第十四条 省级疾病预防控制机构应当做好分发第一类疫苗的组织工作，并按照使用计划将第一类疫苗组织分发到设区的市级疾病预防控制机构或者县级疾病预防控制机构。县级疾病预防控制机构应当按照使用计划将第一类疫苗分发到接种单位和乡级医疗卫生机构。乡级医疗卫生机构应当将第一类疫苗分发到承担预防接种工作的村医疗卫生机构。医疗卫生机构不得向其他单位或者个人分发第一类疫苗；分发第一类疫苗，不得收取任何费用。

传染病暴发、流行时，县级以上地方人民政府或者其卫生主管部门需要采取应急接种措施的，设区的市级以上疾病预防控制机构可以直接向接种单位分发第一类疫苗。

Article 15 Provincial disease prevention and control institutions shall organize the centralized procurement of Class-II vaccines through provincial public resource trading platforms, and county disease prevention and control institutions shall, after purchasing vaccines from vaccine production enterprises, supply them to inoculation entities within their respective administrative regions.

Vaccine production enterprises shall directly distribute Class-II vaccines to county disease prevention and control institutions or authorize enterprises with cold chain storage and transport conditions to distribute them. The enterprises that distribute Class-II vaccines upon

第十五条 第二类疫苗由省级疾病预防控制机构组织在省级公共资源交易平台集中采购，由县级疾病预防控制机构向疫苗生产企业采购后供应给本行政区域的接种单位。

疫苗生产企业应当直接向县级疾病预防控制机构配送第二类疫苗，或者委托具备冷链储存、运输条件的企业配送。接受委托配送第二类疫苗的企业不得委托配送。

县级疾病预防控制机构向接种单位供应第二类疫苗可以收取疫苗费用以及储存、运输费用。疫苗费用按照采购价格

authorization shall not authorize distribution.

County disease prevention and control institutions that supply Class-II vaccines to inoculation entities may charge vaccine fees and storage and transport fees. Vaccine fees shall be charged at the purchase price, and storage and transport fees shall be charged according to the provisions of provinces, autonomous regions, and municipalities directly under the Central Government. The charging information shall be disclosed to the public.

收取，储存、运输费用按照省、自治区、直辖市的规定收取。收费情况应当向社会公开。

Article 16 Disease prevention and control institutions, inoculation entities, vaccine production enterprises, and enterprises that distribute vaccines upon authorization shall abide by the rules on the administration of vaccine storage and transport, and guarantee the quality of vaccines. Vaccines shall be stored and transported in the environment with the prescribed temperature during the entire process, shall not be isolated from the cold chain, and temperature shall be monitored and recorded at regular time. Provincial disease prevention and control institutions shall require the attachment of temperature control labels to the vaccines that are transported in cold chain for a long time and need to be distributed to remote regions.

The rules on the administration of storage and transport of vaccines shall be developed by the competent health department and drug administrative department of the State Council.

第十六条 疾病预防控制机构、接种单位、疫苗生产企业、接受委托配送疫苗的企业应当遵守疫苗储存、运输管理规范，保证疫苗质量。疫苗储存、运输的全过程应当始终处于规定的温度环境，不得脱离冷链，并定时监测、记录温度。对于冷链运输时间长、需要配送至偏远地区的疫苗，省级疾病预防控制机构应当提出加贴温度控制标签的要求。

疫苗储存、运输管理的相关规范由国务院卫生主管部门、药品监督管理部门制定。

Article 17 A vaccine production enterprise shall, when selling vaccines, provide a photocopy of the inspection conformity or examination and approval certificate lawfully issued by the drug inspection institution for each batch of biological products, and affix its enterprise seal. If the enterprise sells imported vaccines, it shall also provide a photocopy of the customs clearance list of imported drugs, and affix its enterprise seal.

A disease prevention and control institution or an inoculation entity shall, when receiving or purchasing vaccines, ask for the testimonials prescribed in the preceding paragraph from the vaccine production enterprise, and preserve them for checking until 2 years after expiry of duration of validity of the vaccines.

第十七条 疫苗生产企业在销售疫苗时，应当提供由药品检验机构依法签发的生物制品每批检验合格或者审核批准证明复印件，并加盖企业印章；销售进口疫苗的，还应当提供进口药品通关单复印件，并加盖企业印章。

疾病预防控制机构、接种单位在接收或者购进疫苗时，应当向疫苗生产企业索取前款规定的证明文件，并保存至超过疫苗有效期2年备查。

Article 18 A vaccine production enterprise shall, in accordance with the HYPERLINK "javascript:ESLC(252632,0)" Pharmaceutical Administration Law and the provisions of the drug administrative department of the State Council, set up true and complete sales records, and retain them until two years after the expiration of validity term of the vaccines for future reference.

A disease prevention and control institution shall, in accordance with the provisions of the competent health department of the State Council, set up true and complete records on purchase, storage, distribution and supply, ensure consistency among bills, account books, goods and payments, and retain them until two years after the expiration of validity term of the vaccines for future reference. The disease prevention and control institution shall, when receiving or purchasing vaccines, request the temperature monitoring records during the entire process of vaccine storage and transport; and if the records on temperature monitoring during the entire process cannot be provided or temperature control fails to satisfy the relevant requirements, the disease prevention and control institution shall not receive or purchase the vaccines, and shall immediately report it to the drug administrative department and competent health department.

第十八条 疫苗生产企业应当依照药品管理法和国务院药品监督管理部门的规定，建立真实、完整的销售记录，并保存至超过疫苗有效期2年备查。

疾病预防控制机构应当依照国务院卫生主管部门的规定，建立真实、完整的购进、储存、分发、供应记录，做到票、账、货、款一致，并保存至超过疫苗有效期2年备查。

疾病预防控制机构接收或者购进疫苗时应当索要疫苗储存、运输全过程的温度监测记录；对不能提供全过程温度监测记录或者温度控制不符合要求的，不得接收或者购进，并应当立即向药品监督管理部门、卫生主管部门报告。

Chapter III Inoculation with Vaccines

第三章 疫苗接种

Article 19 The competent department of health under the State Council shall formulate and promulgate the rules on vaccination work, and shall, according to the national standards of vaccines, and the information on the surveys on epidemiology of infectious diseases, formulate and promulgate the immunity procedures for the vaccines included into the State's immunity planning, and the immunity procedures or guiding principles for use of other

第十九条 国务院卫生主管部门应当制定、公布预防接种工作规范，并根据疫苗的国家标准，结合传染病流行病学调查信息，制定、公布纳入国家免疫规划疫苗的免疫程序和其他疫苗的免疫程序或者使用指导原则。

省、自治区、直辖市人民政府卫生主管部门应当根据国务

vaccines.
The competent health department of the people's government of a province, autonomous region, or municipality directly under the Central Government shall, according to the immunity procedures and the guiding principles for use of the vaccines, which are formulated by the competent department of health under the State Council, and in light of the situation on spread of infectious diseases within its administrative region, formulate the inoculation program for its region, and report it to the competent department of health under the State Council for archival purposes.

院卫生主管部门制定的免疫程序、疫苗使用指导原则，结合本行政区域的传染病流行情况，制定本行政区域的接种方案，并报国务院卫生主管部门备案。

Article 20 The disease prevention and control institutions at all levels shall, upon their respective duties, and according to the State's immunity planning or inoculation program, carry out propagandas, trainings, technical guidance, monitoring, appraisals, epidemiological surveys and emergent treatment, etc. related to vaccination, and make records thereof in accordance with the provisions of the competent department of health under the State Council.

第二十条 各级疾病预防控制机构依照各自职责，根据国家免疫规划或者接种方案，开展与预防接种相关的宣传、培训、技术指导、监测、评价、流行病学调查、应急处置等工作，并依照国务院卫生主管部门的规定作好记录。

Article 21 An inoculation entity shall meet the following conditions:

第二十一条 接种单位应当具备下列条件：

(1) Having a medical institution practicing permit;

（一）具有医疗机构执业许可证件；

(2) Having practicing doctors, assistant practicing doctors, nurses or village doctors who have accepted the professional vaccination trainings organized by the competent health department of a people's government at the county level and who are assessed to be qualified; and

（二）具有经过县级人民政府卫生主管部门组织的预防接种专业培训并考核合格的执业医师、执业助理医师、护士或者乡村医生；

(3) Having the refrigerating facilities or equipment and refrigerating custody systems which conform to the administrative rules on storage and transport of vaccines.
An urban medical and health institution undertaking vaccination work shall set up an outpatient ward for vaccination.

（三）具有符合疫苗储存、运输管理规范的冷藏设施、设备和冷藏保管制度。
承担预防接种工作的城镇医疗卫生机构，应当设立预防接种门诊。

Article 22 An inoculation entity shall undertake the vaccination work within its own responsible area, and accept the technical guidance provided by the local disease prevention and control institution at the county level.

第二十二条 接种单位应当承担责任区域内的预防接种工作，并接受所在地的县级疾病预防控制机构的技术指导。

Article 23 An inoculation entity that receives Class-I vaccines or purchases Class-II vaccines shall request records on temperature monitoring during the entire process of vaccine storage and transport, set up and retain true and complete receipt and procurement records, and ensure consistency among bills, account books, goods and payments. If the records on temperature monitoring during the entire process cannot be provided or temperature control fails to satisfy the relevant requirements, the inoculation entity shall not receive or purchase the vaccines, and shall immediately report it to the drug administrative department and competent health department of the county people's government at the place where it is located.
An inoculation entity shall, in light of the needs in vaccination, formulate the plans on the demands for vaccines of Class 1 and on the purchase of vaccines of Class 2, and shall report them to the competent health department of the people's government at the county level and the disease prevention and control institution at the county level.

第二十三条 接种单位接收第一类疫苗或者购进第二类疫苗，应当索要疫苗储存、运输全过程的温度监测记录，建立并保存真实、完整的接收、购进记录，做到票、账、货、款一致。对不能提供全过程温度监测记录或者温度控制不符合要求的，接种单位不得接收或者购进，并应当立即向所在地县级人民政府药品监督管理部门、卫生主管部门报告。
接种单位应当根据预防接种工作的需要，制定第一类疫苗的需求计划和第二类疫苗的购买计划，并向县级人民政府卫生主管部门和县级疾病预防控制机构报告。

Article 24 An inoculation entity shall, when inoculating vaccines, abide by the rules on vaccination work, the immunity procedures, the guiding principles for use of the vaccines and the inoculation program, and shall announce the varieties and inoculation methods of the vaccines of Class 1 at an eye-catching position of its inoculation place.

第二十四条 接种单位接种疫苗，应当遵守预防接种工作规范、免疫程序、疫苗使用指导原则和接种方案，并在其接种场所的显著位置公示第一类疫苗的品种和接种方法。

Article 25 A medical and health staff member shall, before carrying out the inoculation, inform the inoculated person or his guardian of the variety, function, contraindication and ill response of the inoculated vaccine and the points for attention, inquire about the inoculated

第二十五条 医疗卫生人员在实施接种前，应当告知受种者或者其监护人所接种疫苗的品种、作用、禁忌、不良反应以及注意事项，询问受种者的健康状况以及是否有接

person's health and his information on whether he has contraindication to the inoculation, etc., and shall truthfully record the informed and inquired particulars. The inoculated person or his guardian shall know about the relevant knowledge on vaccination, and shall truthfully provide the information on the inoculated person's health and his contraindication to the inoculation, etc.

Medical and health staff members shall inoculate the persons complying with inoculation conditions, and according to the provisions of the competent health department of the State Council, record the categories and production enterprises of vaccines, the information on the identification of minimum packing units, term of validity, inoculation time, medical and health staff members that perform inoculations, and inoculated persons, among others. Inoculation records shall be retained for not less than five years.

For a person who cannot be inoculated due to his contraindication to the inoculation, the medical and health staff shall propose medical suggestions to this person or his guardian.

种禁忌等情况，并如实记录告知和询问情况。受种者或者其监护人应当了解预防接种的相关知识，并如实提供受种者的健康状况和接种禁忌等情况。

医疗卫生人员应当对符合接种条件的受种者实施接种，并依照国务院卫生主管部门的规定，记录疫苗的品种、生产企业、最小包装单位的识别信息、有效期、接种时间、实施接种的医疗卫生人员、受种者等内容。接种记录保存时间不得少于5年。

对于因有接种禁忌而不能接种的受种者，医疗卫生人员应当对受种者或者其监护人提出医学建议。

Article 26 The State applies a vaccination certificate system to children. Within 1 month after a child is born, his guardian shall go to the inoculation entity undertaking vaccination work at the child's residential locality to obtain the vaccination certificate for the child. The inoculation entity shall check the child's vaccination certificate when carrying out the inoculation, and shall make records.

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第二十六条 国家对儿童实行预防接种证制度。在儿童出生后1个月内，其监护人应当到儿童居住地承担预防接种工作的接种单位为其办理预防接种证。接种单位对儿童实施接种时，应当查验预防接种证，并作好记录。

儿童离开原居住地期间，由现居住地承担预防接种工作的接种单位负责对其实施接种。

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