China Medicinal Biotech Association Newsletter
2nd Quarter，2016

MENU

Policy News

China approves Drug Marketing Authorization Holder Pilot Plan

2016.06.19

China's State Council issued an effective notice dated May 26, 2016, formally authorizing a trial plan for a new Drug Marketing Authorization Holder (MAH) System for ten provinces: Beijing, Tianjin, Hebei, Shanghai, Jiangsu, Zhejiang, Fujian, Shandong, Guangdong, and Sichuan. Pharmaceutical research institutions and individual researchers in these provinces can submit application for clinical trials or Marketing Authorization registration. Applicants obtaining marketing authorizations and approval documents can become MAHs and take legal responsibility for clinical trials, production and marketing, something previously not allowed.

According to PaizaBio's David Deere, who oversees the company's aesptic fill/finish operations in China, this is significant as it approves the use of contract manufacturing organizations (CMOs) to produce drugs in China. Per the State Council's announcement, MAHs without manufacturing capabilities for production must contract with a CMO with qualification to produce approved drugs. MAHs with manufacturing capabilities can use their own facility to produce drugs or may contract production with qualified CMOs. MAHs or applicants can submit additional information, alternate MAH, and change CMO during and after the approval process.

The announcement is a clarification of policy reforms announced by China's Food and Drug Administration (cFDA) in late 2015 designed to accelerate the regulatory review of new drugs and expand options for manufacturing approved drugs. The new policies, which went into effect December 1, 2015, represent major changes in China's drug development and commercialization policies and address the high-volume backlog of drugs awaiting review and approval by the cFDA and foster domestic clinical drug development and manufacturing to international technical and quality standards. Chinese and Western pharmaceutical companies are impacted.

Drugs qualified for MAH trials include:
Therapeutic biologics class 1 - biologics that have not been marketed outside or inside China.
Therapeutic biologics class 7 - biologics that have been marketed outside China but not inside China
Biosimilars
Traditional Chinese Medicine and natural drug classes 1-6
Chemical drug classes 1-4
Chemical drug class 5 - Drug preparations that change the formulation of marketed

drugs without changing administration route.
Chemical drug classes after new chemical registration classification system is enforced (date to be determined).
Approved generic drugs that have quality and efficacy consistency to original drugs. Including chemical drug classes 3-4 after the new chemical registration classification.
Domestic drugs (i) referencing originator drugs that are marketed outside of China, not in China yet, and (ii) consistent with the originator drugs in quality and efficacy.
Domestic drugs (i) referencing originator drugs that are already marketed in China, and (ii) consistent with the originator drugs in quality and efficacy
The MAH Trial period takes effect on this date of plan issuance until November 4, 2018 at which time participants' approval documents will remain valid for the full approval period as issued.
SOURCE: Business Wire

CFDA cuts domestic pharma manufacturing inspections by more than half

2016.06.09

China's Food and Drug Administration (CFDA) was found to have inspected less than half of the number of domestic pharmaceutical manufacturing sites as compared with 2014 according to an annual report from CFDA's Center for Food and Drug Inspection, reports Regulatory Focus.

Despite the decline in site inspections, the percentage of sites experiencing rectification inspections and issuance of warning letters increased by 13%.

The report's findings follow recent decisions by the U.S. FDA to closely watch the Chinese drug market for noncompliant domestic pharmaceutical manufacturers.
SOURCE: BioPharma Dive

China to cut prices of expensive patent drugs

2016.05.24

China's health authority on Friday announced cuts of over 50 percent in the prices of three patent drugs.

The National Health and Family Planning Commission said through pharmaceutical manufacturers have agreed to lower some drugs' prices on condition of bulk purchase.

GlaxoSmithCline (GSK) will reduce the price of Tenofovir Disoprox, a treatment for hepatitis B, from 1500 yuan (229 U.S.dollars) to 490 yuan per month.

Icotinib, an anti-cancer drug made by China's Betta Pharmaceuticals, will be dropped from 12,000 yuan to 5,500 yuan for a month's supply.

AstraZeneca will lower the monthly cost for the anti-cancer Gefitinib from 15,000 yuan to 7,000 yuan.

High prices of imported and patent drugs are a great burden for Chinese patients and the country as a whole.
SOURCE: Xinhua

Top health authority: Immunotherapy to be conducted only for research purposes

2015.10.10

The top health authority vowed to further strengthen regulation and supervision over hospitals and anyone caught violating existing rules will be severely punished, said an online statement issued by the National Health and Family Planning Commission Thursday.

The commission held a teleconference on Wednesday and delivered the tough message to heath officials in administration and management at province, city, and county levels nationwide following a joint investigation into a military cancer clinic where a young man died after receiving the allegedly hyped immunotherapy.

The statement said the immunotherapy must be practiced in China only for scientific research purposes, not commercial clinical use. The treatment that the young man Wei Zexi received is called DC-CIK, a type of the immunotherapy.

Also, the practices for public hospitals subcontracting certain departments to private practitioners are prohibited, it said.

An overhaul into the sector was ordered at the teleconference as well. "The regulation has to be strictly enforced to better secure public health," it said.
(SOURCE: China Daily)

Industrial News

China unveils plan for basic science research

2016.06.15

The National Natural Science Foundation of China (NSFC) published a development plan for the 13th five-year plan period (2016-2020) on Tuesday.

The foundation, a major source of funding for basic research and frontier exploration, has set targets, including one requiring its own investment in basic research to equal that of big-spending countries by 2020, said Gao Wen, vice president of the NSFC. Other goals include as many landmark contributions to the global scientific development as those from S&T competitors, taking a leading role in some fields by 2030, and making major original contributions by 2050, Gao added.

The targets are in concert with national goals in S&T development. China wants to establish itself as one of the most innovative countries by 2020 and a leading innovator by 2030 before realizing the objective of becoming a world S&T power by the 100th anniversary of the founding of the People's Republic of China in 2049.

Spending on basic research rose to 67.1 billion yuan (about 10 billion U.S. dollars) in 2015, but gaps still exist in terms of original research achievements, world-leading scientists and the environment for innovation.

For the 13th five-year plan period, the foundation has picked 118 independent disciplines and 16 interdisciplinary areas as priorities, including quantum information technology, cosmic ray detection, global environmental change, cyber security and optoeletronic devices.

During the previous five-year plan, the NSFC financed nearly 200,000 programs, with around 89 billion yuan from state revenue and 1.75 billion yuan from other sources.

To prevent misuse of funds, the foundation has issued regulations to ensure all the money is used appropriately.
SOURCE: China.org.cn

TaiGen Biotechnology receives market approval from CFDA for Taigexyn

2016.06.13

TaiGen Biotechnology Company, Limited ("TaiGen") announces that the Company has received approval from the China Food and Drug Administration (CFDA) to market the oral formulation of its novel antibiotic.

Taigexyn® (nemonoxacin), in mainland China. It is the first Class 1.1 new drug developed by a Taiwanesecompany to receive market approval in mainland China. It is also the first new drug approval after the CFDA announced the requirement of self-inspection of drug clinical trial data in July 2015.

Dr. Ming-Chu Hsu, Chairman and CEO of TaiGen said, "This is the second market approval for Taigexyn® and will further expand its commercial opportunity. Mainland China is the largest antibiotic market in the world with annual sales exceeding US$12 billion. Taigexyn® 's excellent activity against drug-resistant bacteria and low propensity to resistance development is a valuable tool in fighting the problem of increasing antimicrobial resistance."
SOURCE: PR Newswire

Innovent in $120M bispecifics partnership with EpimAb

2016.06.11

Suzhou-based Innovent Biologics has entered a $120 million partnership with Shanghai-based biotech startup EpimAb Biotherapeutics on bispecific antibodies, building on a landmark deal in the same space reached with Eli Lilly ($LLY) last year.

Under the terms, Innovent will buy the rights to EpimAb's Fabs-In-Tandem Immunoglobulin, dubbed FIT-Ig, a proprietary platform to develop multiple bispecific antibodies for China, a press release explained. It will also get the rights to out-license outside of China in return for an upfront payment to EpimAb, with milestones potentially reaching $120 million before royalties and any earnings from license deals.

In October last year, Innovent expanded a blockbuster pact worth a potential $1 billion with Lilly for rights to as many as three anti-PD-1-based bispecific antibodies for cancer treatments over the next decade in Greater China, with the Indianapolis-based firm holding rights outside of the country.

In January of last year, Innovent raised $100 million in a financing round in what was seen as a milestone for the country's growing biotech industry.

EpimAb, in the release, said its platform generates bispecific antibodies that retain the biological properties of each mAb without major modifications needed to the structure.

“We are very pleased to have gained Innovent as our first licensee,” Chengbin Wu, CEO and founder of EpimAb said in a statement. “Innovent’s world class R&D and biologics CMC capabilities are perfectly suited to develop novel FIT-Ig bispecific antibodies."
SOURCE: Innovent Biologics

Chinese scientists discover new anti-HBV gene

2016.06.09

A gene which can activate the bodys innate immune function and suppress replication of the hepatitis B virus (HBV) has been discovered by Chinese scientists, a finding that provides basis for effective treatment and prevention of the viral infection.

The finding revealed the role that the gene plays in inhibiting the infection of pathogenic microorganisms, state-run Peoples Daily reported.

It also contributes to a better understanding of the molecular mechanism of chronic HBV infection and provides a theoretical basis for effective treatment and prevention.

The research was conducted by a team led by Zhou Gangqiao, a professor at the Academy of Military Sciences, the PLAs medical research institute, the report said.

Zhou led his team to collect more than 10,000 cases of full genetic component-type data, among which they compared the genetic differences between 1,251 cases of chronic HBV infection to 1,057 cases of naturally cleared HBV infection.

Later, from a total of 3,905 cases of infection and 3,356 individuals, the team conducted large-scale identification and validation of the genetic differences, finally coming across a new gene located at chromosome 8p21.3.

Further studies show that the INTS10 gene is capable of suppressing HBV replication.

Currently, around 120 million people in China are carriers of HBV, the report said.
SOURCE: India Today

The first batch of hospitals that can implement stem cell clinical experiment have been published

2016.06.07

The first batch of hospitals that can implement stem cell clinical experiment have been put on record and published by NHFPC and CFDA.

There are 30 hospitals from 16 provinces:
Peking Union Medical College Hospital,
China-Japan Friendship Hospital
Fu Wai Hospital
Peking University People's Hospital
Peking University Third Hospital
The Peking University School of Stomatology
Peking Union Medical College Hospital Blood Disease Hospital
Tianjin Medical School Hospital
Tianjin Huanhu Hospital
The First Affiliated Hospital of Hebei Medical University
The First Affiliated Hospital of Dalian Medical University
Jilin University, China-Japan Friendship Hospital
Fudan University Huashan Hospital
Shanghai Dongfang Hospital
Shanghai Nineth People Hosptal, Shanghai Jiaotong University Medicine School
Renji Hospital Shanghai Jiaotong School of Medicine
Nanjing Drum Tower Hospital, the affiliated Hospital of Nanjing University Medical School
Affiliated Hospital of Nantong University
The Second Affiliated Hospital of Zhejiang University School of Medicine
The First Affiliated Hospital of Nanchang University
The People Hospital of Liaocheng City
The First Affiliated Hospital of Zhengzhou University
Renmin Hospital, Wuhan University
Xiangya Hospital, Central South University
The Third Affiliated Hospital, Sun Yat-Sen University
Zhongshan Ophthalmic Center, Sun Yat-Sen University
GuangdongProvincial TCM Hospital
West China Hospital of Sichuan University
The Affiliated Hospital of Guizhou Medical University
Affiliated Hospital of Zunyi Medical College

Simple drug treatment found to prevent breast cancer, other forms of disease

2016.06.02

A team of international scientists has found that a type of drug already sold on the market can prevent breast cancer and other forms of the disease, the South China Morning Post reported.

Researchers have reportedly tried the drugs on mice and was found to have prevented the growth of breast tumors that result from the mutation of the BRCA1 gene.

According to the study, the drug can block the mechanism that controls the growth of cell and prevent the chance to get any type of breast cancer caused by genetic mutations.

The drug called Denosumab, which is sold as treatment for bone diseases, can block the pathway called rankl/rank.

The new research was led by Professor Josef Penninger, a scientist at the Institute of Molecular Biotechnology at the Austrian Academy of Sciences in Vienna.

The findings of the research, which came after 15 years of work, were published on Tuesday, May 31, in the scientific journal Cell Research.

Penninger said that the use of Denosumab, a rankl/rank pathway-blocking drug, in preventing breast cancer will bring a "revolution" in cancer therapy.

"Our paper introduces the future of breast cancer prevention, and prevention is the big prize in cancer research," the professor told the South China Morning Post. "It could be used for all women and this antibody needs to be injected only two times a year. The clinicians tell me [the drug] is entirely safe."

Rankl, short for "receptor activator of nuclear factor kappa B," is a molecule on a cell's membrane which controls the growth of cells. Rankl passes chemical signals to the molecule to regulate its activities.

For some time, the formation of the the rankl/rank pathway has been thought as the cause of some bone diseases.

Meanwhile, Denosumab, which had been approved safe by the U.S. Food and Drug Administration, is already on the market.

The Penninger team found that blocking the rankl/rank pathway helps prevent the development of BRCA1-driven breast tumors in mice and human cells.

Using Denosumab during the test, breast tumors in lab animals were also wiped out, according to the researchers.

Penninger said they will start the clinical trial in women carrying the BRCA1 mutations "very soon."

"We proposed [five years ago] that a rankl blockade could be used to prevent breast cancer, but it was ignored because I was told one needs data in a high risk cancer population," said Penninger. "Therefore, we started to study BRCA1 mutants because this confers high risk."

Meanwhile, Professor Zeng Yi, who studies breast stem cells at the Chinese Academy of Sciences' Shanghai Institutes for Biological Sciences, has cautioned women against using rankl blocking drugs without extensive clinical trials and until it is proven safe.

She said that blocking the rankl/rank pathway in cells may have unforeseen results for women.

"The FDA approval of a rankl/rank blocking drug does not mean it can be bought and used by every woman. These kind of antibodies are usually in very short supply and extremely expensive," Zeng said.

"The research findings may contain some hope, but it should be treated cautiously by patients and their families," she said.
SOURCE: YIBADA

'Alien' boy gets new skull in pioneering 3D printing surgery

2016.05.31

Doctors creating a detailed model of the boy's misshaped head-who suffered previously because of a rare skull defect.

Now eight months old, the boy known as Xiao Yu, is now recovering following the successful surgery.

Craniosynostosis, which is estimated to affect six babies in every 10,000, causes the joints between the patient's skull bones to close prematurely before the brain is fully formed.

More worrying than the effect on the subject's appearance, however, is the fact that the condition can impair brain development -which could cause seizures and even death.

Xiao Yu was put in the care of Dr Bao Nan and his colleagues at the Shanghai Children's Medical Center in East China.

Now eight months old, the boy known as Xiao Yu, is now recovering following the successful surgery.
SOURCE: Daily Star

Chinese premier stresses reform, innovation

2016.05.25

Chinese Premier Li Keqiang has highlighted reform and innovation to upgrade growth during his visit to Shiyan and Wuhan in central China's Hubei province on Monday and Tuesday.

Reforms of state-owned enterprises should be carried out consistently and the market should be invigorated so that enterprises can be real market entities, he said when visiting a heavy truck manufacturer in Shiyan.

Independent innovation should be highlighted to sharpen competitive edges, he added. Digestion of excessive production capacity is a key task in supply-side structural reform and inefficient production capacity must be cut firmly, he said when visiting Wuhan Iron and Steel (Group) Corp.

He also urged governments at various levels to protect the interests of laid-off workers.

Li visited Wuhan Donghu New Technological Development Zone, a base for China's photoelectron industry and a National Independent Innovative Demonstration Zone.

About 60 percent of Wuhan's economy is underpinned by new dynamics such as high-technology and modern services.

Cultivating new development dynamics and transforming traditional ones can create more jobs and help digestion of steel and coal production overcapacity, he noted.
SOURCE: China Daily

China regulator to launch drug pricing probe in June

2016.05.26

China will carry out wide-ranging pricing inspections on drug firms, hospitals and procurement bodies from June 1, the country's top watchdog said on Friday, extending a tough cost-cutting campaign to reduce the price of healthcare.

The National Development and Reform Commission (NDRC) said in a statement it would carry out the probes from June 1 until the end of October, checking the "pricing behavior" of drug firms and related institutions.

Local media reported earlier this month that China was planning to launch "large-scale and systematic" anti-trust investigation into foreign and local drug firms.

Drug prices have become a hot-button issue for patients and politicians in China, forcing drug companies to re-think their pricing strategy in the country to keep regulators on-side. Britain's GlaxoSmithKline and AstraZenca, along with China's Betta Pharmaceuticals, recently agreed to cut prices on specific drugs by as much as 67 percent.

The NDRC said the investigations would include drug makers, medical institutions, disease prevention and control centers, blood banks, drug bidding platforms, procurement bodies and industry associations.

"The focus will be on abnormal price fluctuations of bulk medicines and various types of drugs," the NDRC said.

"In the worst, most heinous cases, we will use our utmost strength and might to protect the process of fair competition in the medicine market."

China is pursuing an ambitious program of healthcare reforms to improve the public health system and to reduce its reliance on generic and more innovative drugs from overseas.

The country's fast-growing healthcare market is a magnet for global drug makers, medical device firms and hospital operators, all looking to take a slice of a healthcare bill that is expected to hit $1 trillion by 2020, according to McKinsey & Co.
SOURCE: Reuters

China to have more organ transplantation hospitals

2016.05.16

China will increase the number of hospitals conducting organ transplants to 300 in the next five years, said medical expert Huang Jiefu, on Sunday.

According to Huang, the number of donation coordinators, whose job is to convince relatives of potential donors and help with the entire process of donation, will double in the same period.

Currently organ transplants are performed in only 169 hospitals, said Huang, head of a national organ donation and transplant committee and former vice health minister, at a forum in Wuhan, capital of central China's Hubei province.

China now has the most registered organ donors in Asia and the second highest number globally. Each year, about 300,000 patients need transplants but last year only 2,766 people donated major organs after death, almost double the number in 2014, and 10,057 transplants were performed.
SOURCE: XInhua

Beijing confirms first imported Zika case

2016.05.16

The first imported case of Zika virus infection in Beijing was reported on Sunday, the capital's health and family planning commission said in a statement.

The patient, a 29-year-old female from eastern Shandong Province, developed a skin rash and a fever in Venezuela on May 11 local time and returned to China on May 13 Beijing time.

She was tested positive for the virus on Sunday and is currently receiving treatment in hospital.But experts from the commission said further spreading of the disease in Beijing is relatively low.
SOURCE: Xinhua

Clinical use of disputed immunotherapy for cancer is banned

2016.05.07

The National Health and Family Planning Commission emphasized on Thursday that the clinical use of the disputed immunotherapy for cancer treatment is banned, according to a China Daily report.

The top health authority released the statement after it received a public outcry when a young man named Wei Zei died after receiving such treatment at a military hospital in Beijing.

According to the report, "the hospital was found to have outsourced its cancer treatment to a for-profit private company."

This is why the health authority also reiterated that the subcontracting of public hospitals' departments to private entities is also banned.

According to the commission, immunotherapy "has never been approved as a formal therapeutic tool for treatment in China." It can only be practiced for purely scientific research.

Nonetheless, the statement from the commission noted that their approval is required to conduct such research. This is governed by a regulation issued in 2015 that tackles "third-category medical technologies," or those that are considered experimental, risky or uncertain.

The regulation stated that those who agree to participate in the research must be fully informed and that the treatment must be free of charge.

Immunotherapy helps boost patients' immune system in order to fight cancer. It includes many types including DC-CIK, the one received by the young man.

According to the man's parents, they had spent over 200,000 yuan for the treatment at the Second Hospital of Beijing Armed Police Corps.

Insiders revealed that despite the existence of government bans, some public hospitals still provide immunotherapy.

With this, the health commission reiterated that the regulation should be "strictly enforced to better secure public health."

The commission also noted that the military hospitals are under the jurisdiction of the health bureaus of the Central Military Commission and the National Armed Police Force, not by government health authorities.

Currently, the two bodies are jointly probing the hospital involved in Wei's death.
SOURCE: YIBADA

Equipment taking aim at cancer

2016.04.28

The country's first heavy-ion medical accelerator is expected to be used in cancer radiotherapy by the end of the year.

Heavy-ion cancer therapy, a cutting edge radiotherapy approach, kills malignant tumors by irradiating them with high-energy beams produced by a large accelerator.

Developed by the Modern Physics Institute at the Chinese Academy of Sciences and a subsidiary company in Gansu province, the accelerator still has to pass a clinical trial, according to Xiao Guoqing, the institute director.

"It's a great milestone as it marks an end to China's long-term dependence on imported large-scale radiotherapy equipment," he said.

The development of the accelerator started in 2012.
Currently, only the United States, Germany and Japan produce such accelerators.
For the coming clinical trials, about 30 patients will be recruited in Gansu and "if everything runs smoothly, it's expected to formally receive patients by the end of the year", said Ye Yancheng, head of the Wuwei Cancer Hospital, which will conduct the trials with another two hospitals in the province.

Five types of cancer, including brain, liver and prostate, will be targeted in the trial, he added.

The public hospital in Wuwei, a small city about three hours' drive from Lanzhou, capital of Gansu, has bought the first machine under contract with the developer for 550 million yuan ($84.6 million), he said. Local governments and several other private companies also invested.

A subsidiary hospital with 1,600 beds, Gansu Heavy Ion Cancer Center, is under construction. It will receive at least 2,000 patients each year, he added.
"Cancer patients from abroad are welcome as well," Ye said.

According to Ye, top radiotherapists from across the world will be hired, and the treatment will be cheaper than in industrial countries.

It will also serve research purposes for the nation's radiotherapists, he added.

Each year, more than 3 million people develop cancer in China and about 50 to 70 percent of patients need radiation therapy, according to Xia Tingyi, director of the Cancer Center of the Air Force General Hospital in Beijing.

Some Chinese patients have been going overseas seeking advanced radiation therapy, he added.

Manfred Herbst, director of the Rinecker Proton Center in Munich, Germany, told China Daily that they mainly received patients from Australia, South Africa and the US.

Three years ago, the center began to receive 50 to 80 patients a year from China, he said.
"The number has been constantly increasing and we have an international patients service department helping them," Herbst said.

In May, the first heavy ion and proton center opened in Shanghai with a machine purchased from Germany for about 2 billion yuan. A typical course of radiation procedure costs nearly 278,000 yuan.
SOURCE: China Daily

Experiments envision HIV immunity

2016.04.28

Chinese scientists are working on new projects inspired by the documented case of a man who was cured of AIDS. They hope eventually find a way to ensure that humans are born with immunity to the disease.

Nine years ago, a 41-year-old man, who has since been dubbed the "Berlin patient", was close to death and in the advanced stages of both AIDS and leukemia. Doctors gave him a stem cell transplant from an HIV-resistant donor, and miraculously cured both conditions, making him arguably the first person ever to be cured of AIDS.

The remarkable case shed light on CCR5 - a receptor in humans that helps HIV enter cells. The bone-marrow transplant had changed the Berlin patient's gene to a mutation called CCR5-delta32, which blocks HIV.

With new gene technologies now available, Chinese scientists have recently moved forward with attempts to modify the CCR5 gene in embryos, advancing their drive to ensure humans are born already immune to HIV.

In the latest case, researchers from the Third Affiliated Hospital of Guangzhou Medical University used a gene editing technique named CRISPR/Cas to attempt to replace the CCR5 gene in 26 human embryos. The researchers tried to give the embryos the HIV-resistant mutation. Four embryos were successfully edited, while the other 22 cases failed to produce the desired results.

The research was reported in the Journal of Assisted Reproduction and Genetics. "In this study, we demonstrated that the HIV-resistant mutation could be introduced into early human embryos through the CRISPR system," said Fan Yong, a researcher at the institution and an author of the paper.

The CRISPR/Cas gene editing technique, better known as the "molecular Swiss army knife", is a technology developed by US scientist Jennifer Doudna and French scientist Emmanuelle Charpentier in 2012.

Since then, scientists around the world have been using the technology to edit animals' genes in the laboratory.

Huang Junjiu, a biologist at Sun Yat-sen University in Guangzhou, was the first to try the technique on embryos. He reported his experiment on 71 embryos in Nature magazine in April 2015.

Despite the fact that Huang's team used embryos collected from fertility clinics that could not have progressed to live births, their work sparked a global debate on the ethics of such research.

In December, representatives from more than 20 countries gathered for a meeting organized by scientists from China, the US and the UK to discuss these ethical issues. "Our experiments have gone through an ethical review at our hospital. Unlike the UK, China currently does not have a government authority that accepts and examines applications for this kind of research," Fan said.

Scientists also tried to use CRISPR/Cas as a "molecular knife" therapy to cut off HIV within cellular DNA. But a study published in the US journal Cell earlier this month found that the virus can quickly develop resistance to the gene editing technique.
SOURCE: NHFPC

Govt strengthens vaccine oversight

2016.04.26

Chief government officials should resign if serious vaccine violations occurred in their jurisdictions, according to a revised regulation approved by the State Council, China's Cabinet, ahead of National Children's Inoculation Day, which fell on Monday.

The revision of the previous regulation on the management of vaccines was made after a scandal involving 570 million yuan ($88 million) worth of Category 2 vaccines that had been stored improperly and sold across China.

Category 2 vaccines are considered optional.

The regulation was passed on Saturday and took effect immediately, the report said. It intensifies management rules for vaccines, including their transportation and storage, and increases punishments for violators.

China will also raise the amount of compensation paid to those suffering abnormalities after receiving vaccines. Measures under consideration include the introduction of commercial insurance to improve fairness and efficiency in compensation, the regulation says.

Commercial insurance is expected to play an important role in compensating people for any health problems connected with vaccines, the report said, citing the National Health and Family Planning Commission.

In the past, responsibility for compensation belonged to vaccine producers or to the government.

Although vaccines can provide immunization against certain diseases, they can also cause side effects and result in serious physical harm in some individuals because of a person's health condition, although the chances of developing problems are extremely low, according to experts.

Vaccines represent the primary means in most countries to prevent and control infectious diseases, and parents should get their children vaccinated as required by the government, said Yu Wenzhou, an expert at the Chinese Center for Disease Control and Prevention, which runs a national immunization program.

Major infectious diseases that mostly affect children have been reduced to the lowest level in Chinese history, the National Health and Family Planning Commission, China's top health authority, said on Monday.

The commission also called for the public to continue following national policies and make sure all children receive required vaccines to better prevent diseases.
SOURCE: China Daily

CMBA News

Forum for Innovative Regenerative Medicine visits CMBA

2016.06.04

Forum for Innovative Regenerative Medicine of Japan visits CMBA on June 3rd, which is represented by Mr. Zhang Wanjun, the president of Fuji Biotech (Shanghai). Company. Li Shaoli, vice president of CMBA and Wu Zhaohui, general-secretary of CMBA friendly talk with Mr/ Zhang to discuss how to find the cooperation point of both organizations and promote the development of Asian Pacific region's biotherapy for its administration, technology and industry.

The Forum for Innovative Regenerative Medicine (FIRM) was incorporated to quickly establish social systems to ensure safe and stable access to the benefits of research into regenerative medicine.

4th executive member meeting of the 5th council of CMBA takes place in Beijing

2016.05.17

On May 17, 2016, 4th Executive member Meeting of the 5th council of CMBA takes place in Beijing. Wei Yuquan, the academician of CAS, the chairman of CMBA hosts the meeting. Wu Zhaohui, the secretary-general of CMBA reports CMBA resent works. The attendees approve the application of CMBA Information Publication Administrative Measure, the revision of CMBA branches evaluation, the application of implementation of industrial discipline of cell preparing, raw materials of Calf serum products industry, and the implementation of industrial credit evaluation. The attendees approve the application of foundation of CMBA oral biotech branch and CMBA standardization making work committee through voting. Finally, Chairman of CMBA gives the summary the CMBA will follow "the Silk Road Economic Belt and the 21st-Century Maritime Silk Road" to promote the international cooperation of the medicinal biotech industry and develop standardization of stem cell. immunological cell etc and promote the technique transfer.

National Stem Cell Clinical Research Committee was founded in April

2016.04.28

On April. 28th, 2016, National Stem Cell Clinical Research Committee is founded and the meeting is held in Beijing. Liu Qian, the vice-director of NFHPC and Wu Zhen, the vice minister of CFDA attend the meeting and give speech. Cao Xuetao, the director of the committee gives the speech representing the committee. Meanwhile, the Medical Ethic Committee is also founded.

After the meeting, Stem Cell Clinical Research Committee hold the first meeting, revise the regulatory documents and evaluate the material of hospitals that apply for filing. The suggestive list is launched. CMBA provides the assistance of the work of committee secretary and meeting.

China Medicinal Biotech Association

2nd Quarter, 2016

cmbainternational@163.com

www.cmba.org.cn/EN