NATIONAL MEDICAL PRODUCTS NEWSLETTER

Special Provisions for TCM Registration Released

On Feb 10, the Special Provisions for Traditional Chinese Medicines Registration (hereinafter referred to as the Special Provisions) is issued by China NMPA and will take effect on July 1, 2023.

The Special Provisions consist of 8 chapters and 82 articles, including general provisions, registration classification and marketing approval of TCMs, rational application of empirical evidence for human use, innovative TCMs, modified and new drugs of TCMs, compound prepared preparations of TCMs originated from classic recipes, TCMs with identical name and identical recipes, post-marketing change, registration standards, drug names and packaging labels of TCMs. The Special Provisions is closely related to the newly issued Administration Drug Law. It provides a legal basis for the regulation of TCM registration for vigorously promoting the development of drug regulation through a Chinese path to modernization.

(Oct 20, 2023)

2023 National Meeting on Drug Registration Regulation and Drug Post-Marketing Regulation was Successfully Held in Beijing

On February 1, 2023, the National Meeting on Drug Registration Regulation and Drug Post-Marketing Regulation was successfully held in Beijing, summarizing the work completed in 2022 and the past five years, analyzing the current situation and tasks, and deploying the priorities in 2023. Huang Guo, Member of NMPA Leading Party Members’ Group and NMPA Deputy Commissioner attended the meeting and gave a speech. Li Jie, Director for Drug Safety of NMPA, attended the meeting.

The meeting fully affirmed the achievements made in drug regulation in 2022 and the past five years. In 2022, in the face of complex drug registration, the relevant requirements for the R&D of TCMs are further refined, and the regulation of R&D and registration of innovative TCMs are strengthened.

The Special Provisions fully implements the guidelines of the CPC Central Committee and the State Council on promoting the preservation, innovation and development of TCMs, fully absorbs mature experience in the reform of the drug evaluation and approval system, combines with the practice and exploration of the transformation of TCM achievements in epidemiological prevention and control, and learns from domestic and foreign scientific research in drug regulation, so as to establish a comprehensive regulatory system of TCM registration for vigorously promoting the development of drug regulation through a Chinese path to modernization.

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(Oct 20, 2023)
channel mechanism for drugs, and deepened the reform on review and approval system; carried out special inspection and rectification, enhanced the drug quality and safety regulation; carried out the special rectification for drug safety in a deep-going way and established a mechanism of cracking down on violations and crimes threatening drugs in a centralized manner; developed a regulatory system for online drug sales and improved the drug regulatory institutions and systems; and promoted the modernization of regulatory capacity and successfully passed the WHO NRA assessment. The past five years witnessed great development, great reform and great progress in drug regulation in China. The drug regulatory teams have made all-out efforts to serve the overall situation of epidemic prevention and control, effectively maintained the overall stability of drug safety, actively supported the high-quality development of the pharmaceutical industry, and achieved a series of breakthroughs and landmark achievements. Huang Guo pointed out that drug regulation has embarked on a new journey, which requires a clear understanding of the new situation and the courage to face new challenges. We should earnestly implement the "four stricts" [2012-2015] to continuously safeguard the bottom line of drug safety, deepen the reform on drug review and approval system, and increase the efficiency in drug review and approval as well as regulation according to the working visions of "Strengthening Political Awareness, Enhancing regulation, Ensuring Safety, Promoting Development and Improving People’s Well-being to effectively guarantee safe, effective and accessible medication for the public.

Huang Guo stressed that the drug registration management and drug post-marketing regulation in 2023 should seek progress in five aspects including "COVID-19 Prevention, Control, Risk Resolution, Innovative Development, Capability Enhancement and Forming a Clean Government" while maintaining stability. We should provide R&D services, emergent review and approval and quality regulation for COVID-19 vaccines and drugs and serve the overall situation of epidemic prevention and control. We should strengthen the supervision over key variation, links and fields, and consolidate and improve the actual achievements of special rectification actions, and effectively prevent and resolve safety risks and failure dangers. We should continuously deepen the reform on review and approval system, improve the accelerated marketing of new drugs in urgent clinical need, orphan drugs and pediatric drugs, innovate the regulatory modes and methods and promote high-quality development of the industry. We should improve laws, regulations, and systems, promote the digital, acceptance, review, and approval of drug registration, promote the standardized development of drug inspection system, and improve regulatory efficiency. We should strengthen the construction of the Party committee and the government, establish the mechanism for preventing corruption, and severely punish violations of law and discipline, so as to provide a strong guarantee for promoting the modernization of drug registration with Chinese characteristics.

Feb (1, 2023)

Gumaroninib Tablets Approved with Conditions for Marketing

Recently, the Class I innovative product Gumaroninib tablets of Hubei Biopharma Co., Ltd. is approved with conditions by China NMPA. This drug is indicated for treating the locally advanced or metastatic non-small cell lung cancer (NSCLC) with METEx14 skipping mutation.

Gumaroninib can selectively inhibit the activity of c-Met kinase, thereby inhibiting the proliferation, migration and invasion of tumor cells. The marketing of this drug provides a new treatment option available for patients with locally advanced or metastatic NSCLC with METEx14 skipping mutation.

Apr (20, 2023)

Announcement of NMPA on the Adoption of ICH Guidelines Including S1B (R1); Testing for Carcinogenicity of Pharmaceuticals and E14/ST7 Questions & Answers: Clinical and Nonclinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential (NMPA Announcement No. 33 [2023])

To align the technical standards for drug registration with international standards upon deliberation, the National Medical Products Administration decided to adopt the ICH guidelines including S1B (R1); Testing for Carcinogenicity of Pharmaceuticals and E14/ST7 Questions & Answers: Clinical and Nonclinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential. Relevant issues are announced as follows:

1. Sponsors shall conduct the research with reference to ICH S1B (R1) based on the current ICH S1. ICH S1B (R1) is applicable to any research started since March 22, 2023. At the same time, ICH S1A, S1B, and S1C (R2) are still admissible.

2. The starting time of a research should be determined according to the Good Laboratory Practice (GLP).

Mar (7, 2023)

国家药监局批准盐酸凯普拉生片上市

近日，国家药品监督管理局在对河北石家庄制药集团有限公司生产的盐酸凯普拉生片进行审批后，该药品适用于十二指肠溃疡和反流性食管炎的治疗。

盐酸凯普拉生片是一种新上市的竞争性胃酸抑制剂，通过H2受体拮抗剂（H2RA）抑制胃酸的生成，同时结合质子泵抑制剂（PPI），该药品适用于十二指肠溃疡和反流性食管炎的治疗。
Announcement of NMRA on the Adoption of ICH Guidelines Including S1B (R1): Testing for Carcinogenicity of Pharmaceuticals and E14/STB Questions & Answers: Clinical and Nonclinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential (NMRA Announcement No. 33 [2023])

To align the technical standards for drug registration with international standards, upon deliberation, the National Medical Products Administration decided to adopt the ICH guidelines including S1B (R1): Testing for Carcinogenicity of Pharmaceuticals and E14/STB Questions & Answers: Clinical and Nonclinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential.

Relevant issues are announced as follows:

1. Sponsors shall conduct the research with reference to ICH S1B (R1) based on the current ICH S1. ICH S1B (R1) is adaptable to any research started since March 22, 2023. At the same time, ICH S1A, S1B, and SIC (R2) are still adaptable. The starting time of a research should be determined according to the Good Laboratory Practice (GLP).

2. Since July 31, 2023, E14/STB Questions & Answers shall be adopted for drug clinical studies initiated.

3. Relevant technical guidelines are available on the official website of the Center for Drug Evaluation of NMRA. The Center for Drug Evaluation of NMRA is responsible for relevant technical guidance in the implementation of the Announcement.

It is hereby announced.

National Medical Products Administration
March 20, 2023

Gumarontib Tablets Approved with Conditions for Marketing
Recently, the Class I innovative product Gumarontib tablets of Hubei Biopharma Co., Ltd. is approved with conditions by China NMRA. This drug is indicated for treating the locally advanced or metastatic non-small-cell lung cancer (NSCLC) with METex14 skipping mutation.
Gumarontib can selectively inhibit the activity of c-Met kinase, thereby inhibiting the proliferation, migration and invasion of tumor cells. The marketing of this drug provides a new treatment option available for patients with locally advanced or metastatic NSCLC with METex14 skipping mutation.

(Mar. 20, 2023)

Keverprazan Hydrochloride Tablets Approved for Marketing
Recently, the class I innovative drug Keverprazan Hydrochloride Tablets of Jiangsu Carphar Pharmaceutical Co., Ltd. is approved for marketing by China NMRA. This drug is indicated for treating duodenal ulcer and reflux esophagitis.
The Keverprazan Hydrochloride is a new potassium-competitive acid blocker, which inhibits gastric acid secretion by combining with the K+ binding site on H+-K+-ATPase.

(Feb. 15, 2023)

Gumarontib Tablets Approved with Conditions for Marketing
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Keverprazan Hydrochloride Tablets Approved for Marketing
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(2023-02-01)

Gumarontib Tablets Approved with Conditions for Marketing
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(Mar. 20, 2023)
Leritrelvir Tablets for Treating Covid-19 Infection Approved with Conditions for Marketing

Recently, the class I innovative drug Leritrelvir Tablets (Chinese trade name: 乐唯瑞) of Guangdong Raynovnet Tech Co., Ltd. is approved for marketing with conditions by China NMPA through emergency review and approval procedure in accordance with the relevant provisions of special review and approval prescribed in the Drug Administration Law. The Leritrelvir Tablets are oral small molecule drugs for COVID-19 infection treatment, indicated for adult patients with mild to moderate SARS-CoV-2(COVID-19) infection. Patients should use drugs strictly according to the instructions under the guidance of doctors.

The MAH is asked by NMPA to complete relevant research works of the conditional requirements within a time limit, and submit the follow-up research results as soon as possible.

(Mar 23, 2023)

2023 National Meeting on ADR Monitoring was Successfully Held in Beijing

On April 4, 2023 the National Meeting on ADR Monitoring was successfully held in Beijing, summarizing the monitoring and evaluation of drugs, medical devices and cosmetics nationwide in 2022 and the past five years, analyzing the current situation and tasks, and deploying the priorities in 2023. Zhao Junjun, Member of NMPA Leading Party Members’ Group and NMPA Deputy Commissioner attended the meeting and gave a speech. Zhao Junjun fully affirmed the ADR monitoring and evaluation work in 2022. He pointed out that the national monitoring and evaluation system should continuously enhance the risk monitoring of the drugs and medical devices as well as COVID-19 vaccine for epidemic prevention and control and spare no effort in serving the overall situation of epidemic prevention and control, scientifically conduct the monitoring and evaluation of medicines, medical devices and cosmetics and safeguard the bottom line of drug safety; continuously consolidate the pattern of “One Body, Two Wings” and steadily promote the construction of monitoring and evaluation system, and effectively improve the monitoring and evaluation capacities through benchmarking the international vaccine safety capacity, improving the institutional systems, promoting scientific research and innovation, and promoting publicity and training.

It was stressed in the meeting that 2023 is a crucial year for the implementation of the 15th Five-Year Plan. We should earnestly implement the “four strictest” requirements, steadily promote the implementation of the pharmacovigilance system according to the working visions of “Strengthening Political Awareness, Enhancing Supervision, Ensuring Safety, Promoting Development and Improving People’s Well-Being”, and safeguard the bottom line of drug safety, practically ensure the safe and effective medication for the public, support the high-quality development of the pharmaceutical industry and strive to write a new chapter in the pharmacovigilance with Chinese characteristics.

In the meeting, 7 requirements have been put forward for drug monitoring and evaluation in 2023. First, anchor the goals and stick to them. We should fully recognize the significance of pharmacovigilance and the urgency of establishing a pharmacovigilance system; Second, set prudently from beginning to end and make persistent efforts. We should try our best to solve the overall situation of epidemic prevention and control and continue to give play to the role of monitoring and evaluation in guaranteeing the safety of drugs, medical devices and COVID-19 vaccines for epidemic treatment; Third, give consideration to both the present and the long-term goals. We should realize the capacity building of pharmacovigilance system and ensure the high level of safety in the use of drugs, medical devices and cosmetics with the public with efficient pharmacovigilance, Fourth, people with petty shrewdness attend to trivial matters while those with greater wisdom attend to governance of institutions. We should establish a sound legal system and comprehensively strengthen the construction of a monitoring and evaluation quality management system; Fifth, consolidate the bottom line and correct erroneous ideas at the outset. We should effectively guard against drug safety risks and improve the risk assessment capacity and emergency response capacity for drugs, medical devices and cosmetics; Sixth, keep moving and focus on priorities. We should comprehensively improve our technical support capacity and continuously improve the pharmacovigilance, regulatory scientific research and intelligent monitoring and evaluation of traditional Chinese medicines; Seventh, build consensus and make coordinated improvement. We shall work hard to ensure good exchanges, publicity and training, and stimulate the vitality of social governance through monitoring and evaluation.

(Apr 4, 2023)

2023 China Domestic ECMO Products Approved for Marketing

On February 23, 2023, the Extracorporeal Membrane Oxygenation Auxiliary device and centrifugal pump head of Jiangsu STMED technology Inc. is approved with conditions through emergency review by China NMPA. This product is the third ECMO domestic product granted approval.

During the registration and application process of this product for emergency use, the NMPA establishes an emergency review task force, in accordance with the principle of “unified command, early intervention, fast and efficient, and scientific review and approval”, with specific person in charge, giving guidance during the whole process, to accelerate the marketing and application of this product.

(Dec 23, 2023)

Hybrid Closed Loop Insulin Delivery System Approved for Marketing

Recently, the innovative product Hybrid Closed Loop Insulin Delivery System (MiniMed 670G BLEC) of Medtronic MiniMed is approved by China NMPA. The MiniMed 670G BLEC consists of insulin pump, transmitter and insulin sensor, and possesses two core technologies: one is the hybrid closed-loop algorithm used in auto mode; the other is the electrochemical impedance spectroscopy technology used to check the state of the sensor, so that the glucose sensor has sufficient accuracy. The product continuously monitors the trend of glucose concentration in a continuous intersitial fluid through the glucose sensor worn by the patients. According to the
Leitrelvir Tablets for Treating Covid-19 Infection Approved with Conditions for Marketing

Recently, the class I innovative drug Leitrelvir Tablets (Chinese trade name: 乐瑞克®) of Guangdong Raynovet Biotech Co., Ltd. is approved for marketing with conditions by China NMPA through emergency review and approval procedure in accordance with the relevant provisions of special review and approval prescribed in the Drug Administration Law. The Leitrelvir Tablets are oral small molecular drugs for COVID-19 infection treatment, indicated for adult patients with mild to moderate SARS-CoV-2(2019-CDV) infection. Patients should use drugs strictly according to the instructions under the guidance of doctors.

The MAH is asked by NMPA to complete relevant research works of the conditional requirements within a time limit, and submit the follow-up research results as soon as possible.

(Mar 23, 2023)

2023 National Meeting on ADR Monitoring was Successfully Held in Beijing

On April 24, the 2023 National Meeting on ADR Monitoring was successfully held in Beijing, summarizing the monitoring and evaluation of drugs, medical devices and cosmetics nationwide in 2022 and the past five years, analyzing the current situation and tasks, and deploying the priorities in 2023. Zhao Junying, Member of NMPA Leading Party Members’ Group and NMPA Deputy Commissioner attended the meeting and gave a speech. Zhao Junying fully affirmed the ADR monitoring and evaluation work in 2022. He pointed out that the national monitoring and evaluation system should continuously enhance the risk monitoring of the drugs and medical devices as well as COVID-19 vaccine for epidemic prevention and control and spare no effort in serving the overall situation of epidemic prevention and control; scientifically conduct the monitoring and evaluation of drugs, medical devices and cosmetics and safeguard the bottom line of drug safety; practically ensure the safe and effective medical protection for the public, support the high-quality development of the pharmaceutical industry and strive to write a new chapter in the pharmacovigilance with Chinese characteristics.

In the meeting, 7 requirements have been put forward for drug monitoring and evaluation in 2023. First, anchor the goals and stick to them. We should fully recognize the significance of pharmacovigilance and the urgency of establishing a pharmacovigilance system; Second, set prudently from beginning to ending and make persistent efforts. We should try our best to serve the overall situation of epidemic prevention and control and continue to give play to the role of monitoring and evaluation in guaranteeing the safety of drugs, medical devices and COVID-19 vaccines for epidemic treatment; Third, give consideration to both the present and the long term, and should continually promote the capacity building of pharmacovigilance system and ensure the high level of safety in the use of drugs, medical devices and cosmetics with the public with efficient pharmacovigilance; Fourth, people with petty shrewdness attend to trivial matters while those with greater wisdom attend to government of nations. We should establish a sound legal system and comprehensively strengthen the construction of a monitoring and evaluation quality management system; Fifth, consolidate the bottom line and create a harmonious and peaceful society.

(2023-04-25)

2023 China National Domestic ECMO Products Approved for Marketing

On February 23, 2023, the Extracorporeal Membrane Oxygenation auxiliary device and centrifugal pump head of Jiangsu STMED Technology Inc. is approved with conditions through emergency review by China NMPA. This product is the third domestic ECMO product granted approval. During the registration and application process of this product for emergency use, the NMPA establishes an emergency review task force, in accordance with the principle of “unified command, early intervention, fast and efficient, and scientific review and approval”, with specific person in charge, giving guidance during the whole process, to accelerate the marketing and application of this product.

(2023-02-23)

Hybrid Closed Loop Insulin Delivery System Approved for Marketing

Recently, the innovative product Hybrid Closed Loop Insulin Delivery System (MinMed 670G BLC) of Medtronic MinMed is approved by China NMPA.

The MinMed 670G BLC consists of insulin pump, transmitter and sensor. It possesses two core technologies: one is the hybrid closed-loop algorithm used in auto mode; the other is the electrophysiological impedance spectroscopy technology used to check the state of the sensor, so that the glucose sensor has sufficient accuracy. The product continuously monitors the trend of glucose concentration in subcutaneous interstitial fluid through the glucose sensor worn by the patients. According to the
Collagen Scafrod for Cartilage Repair Approved for Marketing

Recently, the innovative product Collagen Scafrod for Cartilage Repair (COLTRAX CartiRegen) of Ubios Co., Ltd. is approved by China NMPA. This product innovatively adopts the process sterilization during collagen extraction in manufacturing, and removes the immunogenic terminal peptide structure, which enables safe batch production of collagen materials with a complete triple helix structure.

(2022-02-27)

Coronary Artery CT Fractional Flow Reserve Software Approved for Marketing

Recently, the innovative product Coronary Artery CT Fractional Flow Reserve Software of Shanghai Pulse Medical Technology Co., Ltd. is approved by China NMPA. This product calculates the CT fractional flow reserve score based on coronary CT angiography images, intended to assist in evaluating the functional myocardial ischemia status of coronary heart disease patients. It can help clinicians determine whether coronary artery stenosis causes myocardial ischemia and whether patients need further intervention and treatment. As a supplement to conventional imaging examinations, the marketing of corresponding software will further reduce the diagnostic time and expenditure burden on patients. The NMPA will strengthen the post-marketing surveillance of the product to protect the safety of medical devices used by patients.

(2022-02-27)

State Administration for Market Regulation Issued the Provisions for Toothpaste Regulation

Recently, the State Administration for Market Regulation issued the Provisions for Toothpaste Regulation (SAMR Decree No. 71), which shall take effect as of December 1, 2023. Toothpaste is not only a product for daily use, but also a product closely related to people’s health. It has been clearly specified in the Regulations on the Supervision and Administration of Cosmetics newly revised that: “Toothpaste shall be managed with reference to the provisions on cosmetics.” In order to implement the Regulations, standardize the production and distribution activities of toothpaste, strengthen the supervision and administration of toothpaste, ensure the quality and safety of toothpaste, safeguard the health of consumers and promote the healthy development of the toothpaste industry, the State Administration for Market Regulation and the National Medical Products Administration formulated the Provisions for Toothpaste Supervision (hereinafter referred to as the “Provisions”) with adherence to the principles of scientific legislation, democratic legislation and law-based legislation, and based on extensive solicitation of comments, in-depth research and full demonstration. The Provisions consist of 25 articles, mainly including the following contents:

- The Provisions clearly define toothpaste as a paste product applied to the surface of human teeth by means of friction, with the main function of cleaning teeth...

(2022-02-27)

Coronary Artery CT Flow Reserve Software

Recently, the innovative product Coronary Artery CT Flow Reserve Software of Shanghai Pulse Medical Technology Co., Ltd. is approved by China NMPA. This product calculates the CT fractional flow reserve score based on coronary CT angiography images, intended to assist in evaluating the functional myocardial ischemia status of coronary heart disease patients. It can help clinicians determine whether coronary artery stenosis causes myocardial ischemia and whether patients need further intervention and treatment. As a supplement to conventional imaging examinations, the marketing of corresponding software will further reduce the diagnostic time and expenditure burden on patients. The NMPA will strengthen the post-marketing surveillance of the product to protect the safety of medical devices used by patients.

(2022-02-27)

Hemodialysis Urea Clearance Calculation Software Approved for Marketing

Recently, the innovative product Hemodialysis Urea Clearance Calculation software of Beijing InfSoft Co., Ltd. is approved by China NMPA. This is a domestic innovative product with independent intellectual property right, of which the performance is on par with advanced international standards. It is intended for the calculation of urea clearance in adult patients with maintenance hemodialysis, but not for the calculation of residual renal function.

Urea clearance is an important index to measure the adequacy of hemodialysis. At present, the calculation usually adopts the invasive blood collection method, which has some defects such as cumbersome operation and inability to keep continuously calculated, which may lead to anemia in patients. Compared with the blood collection method, the product can calculate the urea clearance rate by combining the existing indexes and hemodialysis treatment parameters of patients, and calculate the simulated body fluid volume of patients according to the local area dynamics model. It has advantages such as non-invasive, simple operation, continuous calculation, and can adjust the dialysis plan in time, and effectively improve the dialysis effect of patients.

The NMPA will strengthen the post-marketing surveillance of the product to protect the safety of medical devices used by patients.

(2022-02-27)

Growth Factor Enzyme Repairing Gel Approved for Marketing

Recently, the National Medical Products Administration approved the Growth Factor Enzyme Repairing Gel of Tianjin Ubecco Co., Ltd (regarded as a new innovative product, which is an enzyme biological therapy agent which is mixed into the matrix. After the implantation of collagen scaffold for cartilage repair, the chondrocytes could be differentiated from BMSCs and migrated and proliferated in the surrounding healthy cartilage tissue. Chondrocyte continuously synthesized collagen and secreted type II collagen, forming new cartilage tissue and further repairing damaged cartilage. During this process, the scaffold gradually degraded, and the degradation products can be absorbed by chondrocytes as nutrients or excreted from the body through metabolism. The existing techniques for repairing cartilage injuries commonly include microfracture surgery, cartilage transplantation, chondrocyte transplantation, and joint replacement. The collagen scaffold for cartilage repair in conjunction with knee microfracture surgery is expected to benefit more patients as the marker of cartilage repair.

The NMPA will strengthen the post-marketing surveillance of the product to protect the safety of medical devices used by patients.

(2022-02-27)
Hemodialysis Urea Clearance Calculation Software Approved for Marketing

Recently, the innovative product Hemodialysis Urea clearance calculation software of Beijing Hifsoft Co., Ltd. is approved by China NMPA. This is a domestic innovative product with independent intellectual property right, of which the performance is on par with advanced international standards. It is intended for the calculation of urea clearance in adult patients with chronic hemodialysis, but not for the calculation of residual renal function.

Urea clearance is an important index to measure the adequacy of hemodialysis. At present, the calculation usually adopts the invasive blood collection method. It has some defects such as cumbersome operation and inability to keep continuously calculated, which may lead to anemia in patients. Compared with the blood collection method, the product can calculate the urea clearance rate by combining the existing indexes and hemodialysis treatment parameters of patients, and calculate the simulated body fluid volume of patients according to the local area dynamics model. It has advantages such as non-invasive, simple operation, continuous calculation, and can adjust the dialysis plan in time, and effectively improve the dialysis effect of patients.

The NMPA will strengthen the post-marketing surveillance of the product to protect the safety of medical devices used by patients.

(2022-02-27)

Coronary Artery CT Fractional Flow Reserve Calculation Software Approved for Marketing

Recently, the innovative product Coronary Artery CT Fractional Flow Reserve Calculation Software of Shanghai Pulse Medical Technology Co., Ltd. is approved by China NMPA. This product calculates the CT fractional flow reserve score based on coronary CT angiography images, intended to assist in evaluating the functional myocardial ischemia status of coronary heart disease patients. It can help clinicians determine whether coronary artery stenosis causes myocardial ischemia and whether patients need further intervention and treatment. As a supplement to conventional imaging examinations, the marketing of corresponding software will further reduce the diagnostic time and expenditure burden on patients.

The NMPA will strengthen the post-marketing surveillance of the product to protect the safety of medical devices used by patients.

(2022-02-27)

Colagen Scaffold for Cartilage Repair Approved for Marketing

Recently, the innovative product Collagen Scaffold for Cartilage Repair (COLTRIX CartiRegen) of Ubosio Co., Ltd. is approved by China NMPA. This product innovatively adopts the process stabilization during collagen extraction in manufacturing, and removes the immunogenic terminal peptide structure, which enables steady batch production of collagen materials with a complete triple helix structure.

This product is mainly composed of collagen, which serves as a biological scaffold to provide space for cell adhesion, proliferation, and migration of autologous bone marrow mesenchymal stem cells (BMSCs). After the implantation of collagen scaffold for cartilage repair, the chondrocytes could be differentiated from BMSCs and migrated and proliferated in surrounding healthy cartilage tissue. Chondrocytes continuously synthesize collagen and secrete type II collagen, forming new cartilage tissue and further repairing damaged cartilage. During this process, the collagen scaffold gradually degrades, and the degradation products can be absorbed by chondrocytes as nutrients or excreted from the body through metabolism.

The existing techniques for repairing cartilage injuries commonly include microfracture surgery, cartilage transplantation, chondrocyte transplantation, and joint replacement. The collagen scaffold for cartilage repair in conjunction with knee microfracture surgery is expected to benefit more patients as the marking of cartilage repair.

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(2022-02-27)

Formulating the CT blood flow reserve calculation software to release in the market.

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The Provisions clearly define toothpaste as a paste product applied to the surface of human teeth by means of friction, with the main function of "cleaning the teeth, ensuring oral hygiene and odourless, which is used for teeth cleaning, tooth whitening, tooth care, breath freshening, etc.

The Provisions also regulate the principles and principles of toothpaste formulation, product labeling, advertising, market supervision and administrative measures.

(2022-02-27)

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Recently, the innovative product Collagen Scaffold for Cartilage Repair (COLTRIX CartiRegen) of Ubosio Co., Ltd. is approved by China NMPA. This product innovatively adopts the process stabilization during collagen extraction in manufacturing, and removes the immunogenic terminal peptide structure, which enables steady batch production of collagen materials with a complete triple helix structure.

This product is mainly composed of collagen, which serves as a biological scaffold to provide space for cell adhesion, proliferation, and migration of autologous bone marrow mesenchymal stem cells (BMSCs). After the implantation of collagen scaffold for cartilage repair, the chondrocytes could be differentiated from BMSCs and migrated and proliferated in surrounding healthy cartilage tissue. Chondrocytes continuously synthesize collagen and secrete type II collagen, forming new cartilage tissue and further repairing damaged cartilage. During this process, the collagen scaffold gradually degrades, and the degradation products can be absorbed by chondrocytes as nutrients or excreted from the body through metabolism.

The existing techniques for repairing cartilage injuries commonly include microfracture surgery, cartilage transplantation, chondrocyte transplantation, and joint replacement. The collagen scaffold for cartilage repair in conjunction with knee microfracture surgery is expected to benefit more patients as the marking of cartilage repair.

The NMPA will strengthen the post-marketing surveillance of the product to protect the safety of medical devices used by patients.

(2022-02-27)

Coronary Artery CT Fractional Flow Reserve Calculation Software Approved for Marketing

Recently, the innovative product Coronary Artery CT Fractional Flow Reserve Calculation Software of Shanghai Pulse Medical Technology Co., Ltd. is approved by China NMPA. This product calculates the CT fractional flow reserve score based on coronary CT angiography images, intended to assist in evaluating the functional myocardial ischemia status of coronary heart disease patients. It can help clinicians determine whether coronary artery stenosis causes myocardial ischemia and whether patients need further intervention and treatment. As a supplement to conventional imaging examinations, the marketing of corresponding software will further reduce the diagnostic time and expenditure burden on patients.

The NMPA will strengthen the post-marketing surveillance of the product to protect the safety of medical devices used by patients.

(2022-02-27)
Announcement of NMRA on Issuing the Provisions for the Supervision and Administration of Online Cosmetic Distribution (NMRA Announcement No. 36 [2023])

In order to further strengthen the regulation on online cosmetic distribution, standardize online cosmetic distribution and ensure the quality and safety of cosmetics, the National Medical Products Administration has formulated the Provisions for the Supervision and Administration of Online Cosmetic Distribution in accordance with the Regulations on Supervision and Administration of Cosmetics and the Provisions for Supervision and Administration of Cosmetic Manufacturing and Distribution, which are hereby promulgated and should come into force as of September 1, 2023.

National Medical Products Administration
March 31, 2023

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Special Provisions for TCM Registration Released

On Feb 10, the Special Provisions for Traditional Chinese Medicines Registration (hereafter referred to as the Special Provisions) is issued by China NMRA and will take effect on July 1, 2023. The Special Provisions contain 8 chapters and 82 articles, including general provisions, registration classification and marketing approval of TCMs, rational application of empirical evidence for human use, innovative TCMs, simplification of new drug application of TCMs, compound preparations of TCMs originated from classic recipes, TCMs with identical name and identical recipes, post-marketing changes, registration standards, drug names and packaging inserts of TCMs, etc. The Special Provisions is closely connected to the newly revised Drug Administration Law and Provisions for Drug Registration. Based on the general provisions for the registration of drug registration, the relevant requirements for the R&D of TCMs are further refined, and the regulation of R&D and registration of innovative TCMs are strengthened.

2023 National Meeting on Drug Registration Regulation and Drug Post-Marketing Regulation was Successfully Held in Beijing

On February 1, the 2023 National Meeting on Drug Registration Regulation and Drug Post-Marketing Regulation was successfully held in Beijing, summarizing the work completed in 2022 and the past five years, analyzing the current situation and tasks, and deploying the priorities in 2023. Huang Guo, Member of NMRA Leading Party Members’ Group and NMRA Deputy Commissioner attended the meeting and gave a speech. Li Bai, Director for Drug Safety of NMRA, attended the meeting.

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2023全国药品注册管理和药品上市后监管工作会议在京召开

2023年全国药品注册管理和药品上市后监管工作会议在京召开。2023年1月21日，国家药监局在国家药品审评核查中心召开2023年全国药品注册管理和药品上市后监管工作会议。会议强调，2023年是全面贯彻党的二十大精神的开局之年，是实施“十四五”规划承上启下的关键一年，是药品安全监管工作大有可为、大有作为的一年，也是药品安全监管工作面临形势复杂、责任重大的一年。会议对2023年全国药品注册管理和药品上市后监管工作进行了全面部署和动员，明确了2023年药品注册管理和药品上市后监管工作的总体要求。