NATIONAL MEDICAL PRODUCTS NEWSLETTER

Headline

NMPA Holds Meeting to Promote PIC/S Accession

On July 27, the Department of Drug Regulation of the NMPA held a meeting in Kunming, Yunnan province to promote access to the Pharmaceutical Inspection Co-operation Scheme (PIC/S). The meeting overviews NMPA current progress of applying for PIC/S accession since this year, analyzes the results and common issues of each provincial-level medical products administration based on their self-assessment on par with the requirements, circulates the comparative analysis between the domestic GMP and the PIC/S GMP Guide, further deploys tasks for the next phase and clarifies the working requirements.

The meeting invites experts from the Department of Health, Hong Kong SAR to explicitly introduce detailed conditions of application documents and specific procedures of on-site evaluation when Hong Kong SAR applying for PIC/S accession, as well as the current situation of drug regulatory system construction and drug inspection in Hong Kong SAR. Officials from the Center for Food and Drug Inspection (CFDI) of the NMPA and provincial-level medical products administrations introduced PIC/S Quality System Requirements for Pharmaceutical Inspectors, PIC/S Risk-Based Inspection Planning and Guidance on Classification of GMP Deficiencies, Quality Risk Management (ICH Q9) guideline, and the construction of a professional and specialized inspector team based on their work experience. The meeting also invites experts to share the comparative study and implementation experience on the PIC/S annex of sterile medicinal products.

The meeting emphasized that provincial-level medical products administrations should enhance their political stance and fully recognize the significance of joining PIC/S in reinforcing the drug inspection capabilities and promoting the standardization and internationalization of drug regulation in China. The meeting requires all relevant institutions to focus on key tasks, strengthen work collaboration, and make every effort to prepare application documents. Each provincial-level medical products administration, in accordance with the deployment of the NMPA, should continuously improve the mechanism for drug inspection, persistently optimize the quality management system of drug inspection, take this opportunity to steadily promote the construction of the drug inspector team and enhance the modernization of drug regulation.

The head of the Department of Drug Regulation of the NMPA, the leaders of CFDI and China Center for Food and Drug International Exchange, and relevant responsible persons of NMPA special team for PIC/S accession attend the meeting.

The heads of key provincial-level medical products administrations, and directors of manufacturing regulation divisions and heads of drug control institutions of provincial-level medical products administrations also attend the meeting.

(July 29, 2023)

Published by
China Center for Food and Drug International Exchange

2023. Volume 5
Qijiao Tiaojing Granule Approved for Marketing by China NMPA

Recently, the new traditional Chinese medicine (TCM) compound preparation Qijiao Tiaojing Granule of Hunan Anbang Pharmaceutical Co., Ltd. was approved for marketing by China NMPA. The drug is composed of nine ingredients, including Radix Astragali, Colla Corii Asini, Radix Codonopsis, and Radix Paoniae Alba, etc., which have the effect of nourishing Qi, replenishing blood, stopping bleeding, and regulating menstruation. It is indicated to treat prolonged menstrual periods caused by intrauterine device insertion with TCM syndrome differentiation of Qi and blood deficiency.

Sheng Ge Bushen Capsule Approved for Marketing by China NMPA

Recently, the Category 1.1 innovative traditional Chinese medicine (TCM) Sheng Ge Bushen Capsule of Xinjiang Huachen Biological Pharmaceutical Co., Ltd. was approved for marketing by China NMPA. Randomized, double-blinded, parallel group, placebo-controlled, and multicenter clinical trials were conducted on this drug. The results showed that the difference between the score of the primary efficacy endpoint HAMD-17 and the baseline demonstrating the efficacy in the experimental group was better than that in the placebo-controlled group. The medicine which nourishing Qi, replenishing Yin, and tonifying kidney, is indicated to treat mild to moderate depression with TCM syndrome differentiation of Qi and Yin deficiency, and kidney Qi deficiency. The marketing of this drug provides another treatment option for patients with depression.

TCM Compound Preparation Pipa Qingfei Granules Approved for Marketing by China NMPA

Recently, another traditional Chinese medicine (TCM) compound preparation Pipa Qingfei granules regulated as one of the ancient classic formula which is a category 3.1 innovative TCM is approved for marketing through technical evaluation. The formula of this TCM is derived from the Yi Zong Jin Jian (Golden Mirror of Medicine) by Wu Qian, and contained in the Directory of Ancient Classic Formulae of Traditional Chinese Medicine (the first directory). The marketing authorization holder of this TCM is Jilin Aodong Tiansan Pharmaceutical Co., Ltd.

As recorded in Yi Zong Jin Jian, "this syndrome is caused by the blood heat in lung meridian. It usually generates pimples on face and nose that are shaped like millet bran, red and with swelling pain and broken out with white thick pus. As the course of disease developing, it becomes white, shaped like white millet bran. It is advisable to orally take Pipa Qingfei decoction." The Chinese patent medicine Pipa (Poliol Erictobryctae) Qingfei (lung-clearing) decoction has the effects of clearing the heat of lung meridian and is indicated for acne by wind invading lung.
causing syndrome of pimples on face and nose, red and with swelling pain, broken out with thick pus or causing dry patches. The marketing of this TCM variety will be conducive to promoting the wider use of ancient classic formulae in clinical practice, enhancing the influence of TCM in clinical service and bringing more convenience to drug availability for patients.

(Taftolecim Injection Approved for Marketing by China NMPA)

Recently, the Taftolecim Injection (trade name: SINTBILO®) of Inovent Biologics (Suzhou) Co., Ltd. is approved by China NMPA. The indication is: for the treatment of adult patients with primary hypercholesterolemia (including heterozygous familial and non-familial hypercholesterolemia) and mixed dyslipidemia, who cannot achieve the recommended target of low-density lipoprotein cholesterol (LDL-C) even after receiving moderate or high doses of statin therapy. It is used in combination with statins, or with statins and other lipid-lowering therapies. The Taftolecim Injection is a proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor. By inhibiting PCSK9, blocking the binding of plasma PCSK9 to low-density lipoprotein receptor (LDLR), thereby preventing the endocytosis and degradation of LDLR, it increases the expression level and quantity of LDLR on the cell surface, increases LDLR reuptake of LDL-C, reduces circulating LDL-C levels and ultimately achieves the goal of reducing blood lipids. The marketing of this variety provides new treatment options for lipid-lowering treatment.

(Aug 16, 2023)

(Sunvozertinib Tablets Approved for Marketing by China NMPA) Recently, the Category 1 innovative drug Sunvozertinib Tablets (Chinese trade name: 舒沃替尼) of Dizal (Jiangsu) Pharmaceutical Co., Ltd. is approved by China NMPA. This drug is indicated for adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) who have experienced disease progression during or after platinum-containing chemotherapy, or are intolerant to platinum-containing chemotherapy, and have been confirmed to have an insertion mutation in the epidermal growth factor receptor (EGFR) exon 20 through testing. Sunvozertinib is an EGFR tyrosine kinase inhibitor. The marketing of this drug provides a new treatment option for adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with EGFR 20 exon insertion mutations.

(Aug 23, 2023)
NMPA Announcement on Adopting ICH Guidelines Q12

To align the technical standards for drug registration with international standards, the NMPA has decided to adopt the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) Guidelines Q12: Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management. The relevant items herein are hereby announced as follows:

1. The guidelines of Q12 provide a new approach and regulatory tool for post-approval changes for drugs. Applicants can conduct change management in accordance with the relevant regulations, provisions and guiding principles of change management in China, or use the new approach provided by Q12 when submitting marketing applications and/or supplementary applications. Before implementing Q12, applicants should fully evaluate whether they have the research and development foundation and implementation conditions applicable to the guidelines.

2. Starting from August 25, 2023, there will be a transition period of 24 months for the implementation of Q12. For drug registration applications during the transition period, if the applicant adopts Q12 for change management, please communicate and exchange with the Center for Drug Evaluation (CDE) of NMPA before submitting the drug registration application according to the relevant requirements of the management measures for communication and exchange of drug research and development and technical review (the NMPA CDE Notice No. 48 of 2020). Before the end of the 24 month transition period, it will be determined whether to extend the transition period based on the practical conditions during the transition period.

3. The Chinese and English versions of Q12 guidelines can be found at the CDE website. The CDE of NMPA is responsible for providing relevant technical guidance during the implementation of this Announcement.

National Medical Products Administration
August 25, 2023
(Aug 25, 2023)

NMPA Announcement on Adopting ICH Guidelines S12

To align the technical standards for drug registration with international standards, the NMPA has decided upon deliberation to adopt the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) Guidelines S12: Nonclinical Biodistribution Considerations for Gene Therapy Products (hereinafter referred to as S12). The relevant items herein are hereby announced as follows:

Nonclinical studies starting from the issuance of this Announcement shall be applied to S12. The determination of the starting date of nonclinical studies shall be in accordance with the relevant provisions of the Good Laboratory Practice for drugs. The guidelines can be found at the website of the Center for Drug Evaluation (CDE) of the NMPA. The CDE of NMPA is responsible for providing relevant technical guidance during the implementation of this Announcement.

National Medical Products Administration
August 25, 2023
(Aug 25, 2023)
Narilumab Injection Approved with Conditions for Marketing by China NMPA

Recently, the Narilumab Injection (Chinese trade name: 张立生) of Shanghai JMTC Biotechnological Co., Ltd. is approved with conditions through the priority review and approval procedure by China NMPA. This drug is indicated for the treatment for adult patients with giant cell tumor of bone that is unresectable or where surgical resection is likely to result in severe morbidity.

The Narilumab Injection is a recombinant human anti-receptor activating NF-kB ligand (RANKL) monoclonal antibody. It can inhibit the activity of RANKL through specifically binding to RANKL on the cell membrane, thereby inhibiting its involvement in mediating osteolysis and tumor growth. The marketing of this drug provides a new treatment option for patients.

NMPA Held 2023 ICH in China: Progress and Outlook Symposium

On September 12, NMPA held 2023 ICH in China: Progress and Outlook Symposium in Beijing, to make dialogue on development and cooperation with representatives from domestic and foreign industry associations. Huang Guo, Deputy Commissioner of China NMPA attended and addressed at the meeting.

Huang Guo stated that China is deeply involved in global drug safety governance and continuously deepening international cooperation. Through joining International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) and becoming an ICH management committee member, NMPA has been actively learning from and sharing with international peers, accelerating the coordination and harmonization of regulatory rules, promoting mutual recognition of international regulation, and jointly enhancing the development of the global pharmaceutical industry.

He emphasized that the NMPA is willing to work together with all parties, adhere to the scientific, governance-by-law, international, and modernized path of development, continue to deepen drug regulatory reform and innovation, and accelerate the approval of drugs that are urgently needed on clinical side, so as to further expand external opening up and high-quality international cooperation, jointly foster a good ecosystem for high-quality development of the pharmaceutical industry, and protect and promote public health.

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Artificial Lens Approved for Marketing

Recently, the innovative product Artificial Lens of Alcon Laboratories, Inc. is approved by China NMPA. This product is a single-piece posterior chamber intraocular lens, of which the front surface center adopts a patented wavefront shaping structure. This product is suitable for adult patients with corneal astigmatism who have undergone extracapsular cataract extraction to remove the cataract lens. In the first phase, the product is implanted to correct vision by expanding the focal depth, which means expanding the visual range from long distance to functional close range while maintaining considerable distance vision, and therefore reducing patients' dependence on glasses. The marketing of this product will provide more options for clinical treatment. The NMPA will strengthen the post-marketing surveillance of the product to protect the safety of medical devices used by patients.

(Apr 20, 2023)

Zirconium Niobium Alloy Femoral Head Approved for Marketing

Recently, the innovative product Zirconium Niobium Alloy Femoral Head of Suzhou MicroPort Orthopedics Medical Technology Co., Ltd. is approved by China NMPA. The zirconium niobium alloy femoral head is used in conjunction with the components of hip joint prosthesis from the same series of this enterprise, applicable for total hip joint replacement. This product adopts zirconium niobium alloy that meets international standards (ASTM F2384), and forms a ceramic layer on the surface through gradient oxidation, which can reduce the wear rate of highly cross-linked polyethylene liner and reduce the revision rate of hip joint prostheses. Compared with cobalt chromium alloy femoral heads commonly used in clinical practice, this product can reduce metal ion precipitation and joint surface wear. Compared with ceramic femoral heads, it can reduce the risks such as prosthesis fragmentation and joint noise. The marketing of this product will provide more options for clinical treatment. The NMPA will strengthen the post-marketing surveillance of the product to protect the safety of medical devices used by patients.

(June 16, 2023)

Single-port Laparoscope Surgery System Approved for Marketing

Recently, the innovative product Single-port Laparoscope Surgery System of Beijing SurgiRobotics Company Limited is approved by China NMPA. This product is composed of a doctor's console, a patient's operating platform, a three-dimensional electronic abdominal endoscope, surgical instruments and accessories. It is applied for laparoscopy in urinary surgery. It is the first domestic single-port laparoscope surgery system filling the gap. The surgical instruments of this product adopt innovative technologies that are internationally pioneered and possess independent intellectual property rights, featuring with technological advantages such as wide range of motion, strong load capacity, and high reliability.

NATIONAL MEDICAL PRODUCTS NEWSLETTER
Venous Stent System Approved for Marketing

Recently, the innovative product Venous Stent System of Suzhou Inomed Medical Device Co., Ltd. is approved by China NMPA. The venous stent system consists of a self-expanding nickel titanium alloy stent and a delivery system. The self-expanding stent is woven from nickel titanium wire, featured with flexibility, bending resistance, and fatigue resistance. This product has a unique self-compensative structure after release to ensure that the accurate release shape of venous stents during surgery. It also has a recyclable function, which can withdraw 90% of the stent length back to the delivery system before it is fully pushed out, which enables reposition and release for one more time, to solve abnormal issues during release and improve product safety.

Medical Electronic Linear Accelerator Approved for Marketing

Recently, the innovative product Medical Electronic Linear Accelerator of Xian OUR UNITED Corp. is approved by China NMPA. This product is composed of a frame, beam generation module, beam shaping module, treatment bed, image guidance system, and control system, which is the first of its kind domestically. It is applied to provide image-guided 3D conformal radiotherapy, intensity-modulated radiotherapy, volume-modulated radiotherapy, and stereotactic body radiotherapy for solid tumors and lesions suitable for radiotherapy in the human body. This product applies a circular frame with conductive slip rings, which can shorten treatment time and improve treatment efficiency for clinically complex patients who require multi-arc continuous radiotherapy. The NMPA will strengthen the post-marketing surveillance of the product to protect the safety of medical devices used by patients.

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Rigid Scleral Contact Lens Approved for Marketing

Recently, the innovative product Rigid Scleral Contact Lens of Shanghai Ai Kangie Medical Technology Co., Ltd. is approved by China NMPA. This product is a daily-wear and large-diameter rigid scleral contact lens (commonly known as "scleral lens"). The lens material is "hydrophilic A", colored in ice blue. This product is composed of four arc segments: optical zone, peripheral central clearance zone, limbus corneal zone, and scleral landing zone. During clinical testing, parameter adjustments can be made to each arc segment to obtain a more ideal thickness of the microscopic fluid, improving the patient's visual quality while also protecting corneal tissue. This product innovatively adopts a double sagittal deep asymmetric design, which can better match the asymmetric sclera. The scleral landing area is designed with a reverse curved surface, providing patients with a more comfortable wearing experience. This product is suitable for patients with refractive errors or for those who have +25.00D to -25.00D with corneal regular astigmatism less than 5.00D to correct irregular astigmatism. The marketing of this product will provide more options for clinical treatment.

The NMPA will strengthen the post-marketing surveillance of the product to protect the safety of medical devices used by patients. (Aug 5, 2023)

Hip Replacement Navigation Positioning System Approved for Marketing

Recently, the innovative product Hip Replacement Navigation Positioning System of Hangzhou Lance Robotics company is approved by China NMPA. This product is composed of a robotic arm trolley, a main console trolley, an optical tracking trolley, a foot switch, a medical electric drill, and surgical tools. It can be used in conjunction with validated hip joint prostheses and surgical tools to assist doctors in completing prosthetic tasks such as acetabulum grinding, femoral osteotomy, and hip joint prosthetic installation during hip replacement surgery. This product is independent intellectual property rights, of which the performance indicators are on par with international standards of the same devices. Compared with conventional hip replacement surgery, surgery with this product can improve surgical positioning accuracy, reduce adverse events and complications, and reduce radiation damage to doctors and patients caused by X-rays. The NMPA will strengthen the post-marketing surveillance of the product to protect the safety of medical devices used by patients. (Aug 11, 2023)

Notes:
- All the Chinese information in the Newsletter is from newspapers and the Internet. All English articles are translated from the Chinese version. In case of any discrepancy, the Chinese version shall prevail.
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China Center for Food and Drug International Exchange (CCFIE)

Hard X-ray Articular Joint Navigation System Approved for Marketing

Recently, the Shanghai Medical Administration approved the Hospitals' products called "Hard X-ray Articular Joint Navigation System". The product is a joint-type hard X-ray navigation system. The product is composed of a gantry platform, a target tracking device, a C-arm, a fluoroscopy system, and a computer workstation. The product uses a special calibration method to ensure the accuracy of the navigation system. The product is designed with ergonomics in mind, providing a comfortable experience for surgeons. The NMPA will strengthen the post-marketing surveillance of the product to protect the safety of medical devices used by patients. (Aug 5, 2023)