



Newsletter

Update

May 9, 2020

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Update

Provisions for Drug Registration and Supervision of Drug Production will be Implemented on July 1, 2020

On March 30, 2020, the State Administration for Market Regulation issued the *Provisions for Drug Registration* by order No.27 and *Provisions for Supervision of Drug Production* by order No.28, which shall officially go into effect as of July 1, 2020. These new provisions are the first revision in 13 years since October 2007. The main contents of the two provisions are as follows:

1. Fully Implementing the Market Authorization Holder System

The *Provisions for Drug Registration* explicitly stipulates that applicants shall be the enterprises or drug development institutions which is able to take corresponding legal responsibilities, and overseas applicants shall designate a business entity within China to handle relevant drug registration matters. The applicant will be the drug market authorization holder after it obtains the drug registration certificate. The *Provisions for Supervision of Drug Production* stipulates that holder should establish a system for ensuring the drug quality, managing the full life circle of drug, carrying out post-marketing research, and taking responsibility for the safety and effectiveness and quality of marketed drugs.

2. Optimizing Assessment and Approval Processes

The provisions change the process of drug evaluation, inspection, verification from “series” to “parallel”. Also, four accelerated channels are being set up, which involve breakthrough therapeutic drugs, conditional approval, priority

review and approval, and special approval. For drug application in the priority review and approval process, the review time limit is 130 working days. For orphan drug that requires clinical emergency treatment which has been marketed overseas but not domestically, the review time limit is 70 working days. The clinical urgently needed shortage medicines, orphan drugs, pediatric drugs, major infectious diseases medicines, vaccines urgently needed for disease control, and innovative vaccines are also included in the scope of accelerated listing registration.

3. Regulating Medicines Throughout Their Life Cycles

The provisions intend to enhance the supervision of drug development, registration and post-marketing as well as to strengthen the supervision of drug clinical trial institutions and drug non-clinical research institutions and the relevant requirements of drug safety credit record. The provisions focus on the organic connection between registration and production licensing, inspection, and supervision.

4. Reinforcing Accountabilities

The provisions also try to enhance accountability in the following ways: strictly implementing the corporate responsibility and regulatory responsibilities; refining the obligation of drug development, registration, production; clarifying the division of responsibility and supervisory inspection requirements of regulatory authorities; detailed penalties; and severely cracking down on data fraud and other violations.

AbbVie's Humira® Approved for Clinical Urgent Needed Indication Uveitis in China

On March 24, 2020, the National Medical Products Administration ("NMPA") approved the new indication for AbbVie's Humira (Adalimumab) for the treatment of adult non-infectious intermediate, posterior, and panuveitis. It has become China's first and only approved biological agent for the treatment of this kind of uveitis.

The indications for the approval of Humira for uveitis are mainly based on the results of two global phase III clinical studies VISUAL-I, VISUAL-II, and an open label extension study VISUAL-III. The results of the study showed that the risk of failure of Humira to treat uveitis was significantly reduced, and no new safety risks were found.

Non-infectious intermediate, posterior, and panuveitis are a group of immune-mediated intraocular inflammatory diseases that can lead to complications such as iris adhesions, glaucoma, cataracts, macular edema and retinopathy. Immune-mediated systemic diseases such as psoriasis and ankylosing spondylitis occur together. At present, the main clinical treatment plan is glucocorticoids, but long-term large-scale application of glucocorticoids can cause serious side effects. Humira is an anti-TNF monoclonal antibody that currently treats patients who does not respond adequately to glucocorticoids, need to use glucocorticoids sparingly, or is not suitable for glucocorticoid, and provide such patients a new option. Now Humira has been included in the Drug Catalog of National Basic Medical Insurance, Industrial Injury Insurance and Maternity Insurance. The indication covered includes rheumatoid arthritis, ankylosing spondylitis, and plaque psoriasis.

China Revised Authorization for Registration of Foreign-invested Enterprises

Recently, China published the new revision of Administrative Measures for Authorization for Registration of Foreign-invested Enterprises (the "Draft"). The Draft has been issued for public comment from April 14, 2020 to May 14, 2020. The formal measures are expected to take effect in July.

According to the Draft, the registration of a foreign invested enterprise shall be handled by the State Administration for Market Regulation ("SAMR") or the legally authorized market regulatory department of the local government. The authorized local market regulatory departments shall exercise the registration and administration of foreign invested enterprises in their own name and within the scope of their authorization. Without the authorization of SAMR, they

shall not conduct any work on administration of registration of foreign invested enterprises, no matter in a direct or a disguised manner. The Draft also states SAMR may respond in five different ways if the authorized regulators breach any provision of the measures, including revoking the authorization in part or in whole.

The revision of Administrative Measures for Authorization for Registration clarifies that under the framework of the new Foreign Investment Law of the PRC, SAMR has full authority on the industrial and commercial registration and filing of foreign invested enterprises, instead of the old rules under which commercial filing shall be administered by the Ministry of Commerce and industrial and commercial registration shall be administered by the Industrial and Commercial Bureau.

China Issued Measures to Improve Administration of Foreign Exchange

The State Administration of Foreign Exchange (“SAFE”) has recently issued the *Notice on Optimizing Foreign Exchange Administration to Support Development of Foreign-related Business* (the “Notice”), which will take effect on June 1, 2020. The Notice aims to simplify the procedures on foreign exchange administration, improve cross-border trade and investment facilitation, and support the resumption of work and production actively.

The Notice focuses on two aspects: the optimization of foreign exchange business management and improvement of foreign exchange business services, including a total of eight measures:

- 1) promoting the reforms to facilitate capital account income payments nationwide;
- 2) canceling the registration of special-purpose refund of remittance business;
- 3) simplifying the registration administration of some capital account business;
- 4) loosening the purchase of foreign currency loan repayment associated with export business;
- 5) facilitating the use of electronic documents and certificates in foreign exchange transactions;
- 6) improving banks’ foreign exchange settlement in cross-border e-commerce;
- 7) relaxing the business audit endorsement procedures; and
- 8) supporting banks in providing innovative financial services.

Pilot Cross-border Transfer of Domestic Trade Financing Assets in Lin-Gang Special Area of China (Shanghai) FTZ

On March 31, 2020, Shanghai Head Office of the People’s Bank of China announced the launch of the pilot project for cross-border transfer of domestic trade financing assets in Lin-Gang Special Area.

In Shanghai, all commercial banks are allowed to carry out cross-border transfer business of domestic trade financing assets in the Lin-Gang Special Area. In the initial stage of the pilot project, the transferable assets include forfaiting and risk participated assets based on the domestic L/C (letter of credit) trade settlement.

This pilot policy is conducive to further enrich the two-way cross-border circulation channels of Renminbi and to satisfy the needs of overseas institutions for allocating high-quality domestic financial assets.

Article(s)

Summary of Coronavirus-Related Government Assistance Policies in China

by Jenny Chu

As a result of the recent outbreak, many enterprises in China are looking for ways to cut their losses and get government assistance. We've compiled a list of some of the most important assistance policies that the Chinese government provides to businesses.

I. General Assistance

A. Tax

1. From March 1 to May 31, 2020, for small-scale VAT taxpayers in other regions except for Hubei, the rate of VAT levy shall be 1% instead of 3%.
2. From February 2020, micro, small and medium enterprises in provinces except for Hubei can be exempted from the employer payment of three social insurance contributions. The exemption period is subject to local regulations, but not more than five months.
3. From February 2020, large enterprises in provinces other than Hubei can halve the payment of the three social insurance contributions. The period is subject to local regulations, but not more than three months.
4. From February 2020, according to local specific regulation, enterprises can pay half of workers' medical insurance for certain period.

B. Credit

1. Financial institutions shall make appropriate adjustments in their credit policies, reasonably delay the repayment period of enterprises that are greatly affected by the epidemic, and adopt the method of rapid approval to simplify the process of applying for financing.
2. Financial institutions shall provide appropriate credit support to manufacturing enterprises, small and micro enterprises, private enterprises and other enterprises in key areas, and increase medium-term and long-term loans for manufacturing industries.
3. The government has introduced a series of policies to reduce the overall cost of corporate loans, increase the proportion of credit loans, renewal loans and medium and long-term loans in corporate loans, and increase the first loan rate of enterprises. Financial institutions are responsible for loan approval and post-loan management, and the interest rate of lending with special re-financing funds shall not exceed the last published one-year LPR minus 100 BP. Banks and insurance institutions can lend at rates below the lending rate ceiling. The government will pay a 50% discount to the actual lending rate that enterprises receive to ensure that their actual financing costs fall below 1.6%.
4. For loan principal of micro, small and medium enterprises in trouble due since January 25, 2020, and the loan interest on January 25 and June 30, the banking financial institutions shall temporarily extend the principal and interest repayment arrangement for certain period. The principal and interest repayment date can be extended up to June 30, 2020, without penalty.

II. Assistance for Enterprises in the Prevention and Control of the Epidemic

A. Production enterprises of key materials for epidemic prevention and control

1. Enterprises that manufacture key materials for epidemic prevention and control to expand production capacity and purchase equipment are allowed to deduct the enterprise income tax in a lump sum before tax
2. Enterprises producing key materials for epidemic prevention and control may apply to the competent tax authorities on a monthly basis for full refund of the incremental VAT credit.

3. The list of key producers of materials for epidemic prevention and control shall be determined by the Development and Reform Departments and the Departments of Industry and Information Technology at or above the provincial level.

B. Enterprises focus on epidemic prevention and control

1. Taxpayers' income for key supplies transportation services shall be exempted from VAT.
2. The list of key supplies released by the National Development and Reform Commission includes:

Article	Items
Medical emergency supplies	Protective clothing, isolation clothing, masks, disinfection and sterilization supplies, kits, infrared thermometer and other medical supplies
	Important raw materials and auxiliary materials, important equipment and related supporting equipment for the production of medical materials
	Communications equipment to provide information in response to epidemic prevention
Necessities of life	Tents, quilts, folding wear and other relief materials
	Grain, edible oil, salt, sugar, vegetables, meat, eggs, milk, aquatic products, frozen food and convenience food and other necessities of life of which the market needs to maintain the supply during the epidemic period
	Fodder, fertilizer, vegetable seedlings and other agricultural materials

What's more, the Ministry of Industry and Information Technology also published a detailed list of the classification of medical emergency supplies, including tablets, reagents, sterilizing supplies (and the raw materials, auxiliary materials, production equipment and packaging materials), protective supplies (and the raw materials and production equipment), special vehicles, equipment, instruments (and their key components), and production equipment.

3. Taxpayers providing public transport services, life services, and residents' necessary daily necessities express delivery service shall be exempted from VAT.
The specific scope of public transport services shall be in accordance with the Provisions on the Pilot Project to Replace Business Tax with Value-added Tax.
The specific scope of life service and express delivery service shall be in accordance with the Notes on Sales Service, Intangible Assets and Real Estate.
4. The registration fee of medical device products is exempted for prevention and control products related to novel coronavirus (2019-ncov) entering the emergency approval process of medical devices.
5. The pharmaceutical registration fees are exempted for medicines entering into special approval procedures for medicines, treatment and prevention of novel coronavirus (2019-ncov) pneumonia.
6. The central bank shall guide financial institutions to increase credit support to enterprises in the field of epidemic prevention and control.
7. "Green channel" for the registration and issuance of financial bonds, asset-backed securities and corporate credit bonds issued by financial institutions and enterprises in heavily affected areas and mainly used for epidemic prevention and control shall be established, as well as another "green channel" for the registration and filing of private equity investment funds that plan to invest in medical equipment related to epidemic prevention and vaccine drug production and research and development enterprises.

C. Difficult industries affected by the outbreak

1. Difficult industries affected by the outbreaks including transportation, catering, and accommodation, tourism (referring to travel agencies and related services, tourism scenic spot management) four major categories, the specific judgment criteria in accordance with the current Classification of National Economy Industry.
2. In 2020, the main business income of enterprises in difficult industries shall account for more than 50% of the total revenue (excluding non-taxable income and investment income)
3. The maximum carryover period for losses incurred by an enterprise in difficult industries in 2020 shall be extended from 5 to 8 years.
4. Exemption from the civil aviation development fund payable by airlines.
5. The central bank shall guide financial institutions to provide differentiated and preferential financial services to regions, industries and enterprises that are more affected by the epidemic.

III. Assistance for Technology Enterprises

1. Resident enterprises that have been recognized and registered for technical contracts during the epidemic prevention and control period may log on to the "national online registration system for technical contracts" for online recognition and registration of technical contracts. Paper copies of technical contracts may be deferred until after the outbreak is over.
2. The national information service platform for small and medium-sized technology-based enterprises is open to the public all the time.
3. Local Science and Technology Administrative Departments should take the initiative to coordinate with relevant departments to increase financial support for incubators of science and technology entrepreneurship, and encourage science and technology business incubators, mass innovation Spaces and university science and technology parks to appropriately reduce or reduce the rent of office rental, experimental, scientific research and production premises for incubated enterprises.
4. The local governments shall provide financial support to the scientific and technological enterprises which were greatly affected by the epidemic and had production and operation difficulties.
5. Local Science and Technology Administration Departments need to recommend new technologies, products and services for epidemic prevention and control.

IV. Assistance for Cross Border

1. The bank should open up a shortcut for cross-border RMB business such as importing and donating materials related to epidemic prevention and control.
2. For the import of epidemic prevention and control materials needed by relevant departments and local governments, each branch of the SAFE office shall guide banks within its jurisdiction to simplify the import purchase and payment procedures and materials.
3. For the inward and outward foreign exchange donation to support epidemic prevention and control, the bank may directly handle it through the existing foreign exchange settlement account under current account of the recipient unit, and suspend the requirement of opening a foreign exchange donation account.
4. When an enterprise handles the settlement and payment of foreign exchange from capital account income related to epidemic prevention and control, it is not necessary to submit documents in advance, and the bank shall strengthen the post-inspection on the authenticity of the enterprise's capital use.

5. Enterprises may cancel the quota of foreign debt borrowing, etc., and may apply for registration of foreign debt online to facilitate enterprises to carry out cross-border financing if there is a real need for epidemic prevention and control.
6. Banks should pay close attention to individuals' demand for foreign exchange and encourage them to conduct personal foreign exchange business through online channels such as mobile banking.
7. For other special foreign exchange and RMB cross-border businesses related to the prevention and control of the epidemic, the bank may handle and conduct post-inspection in advance, and report to the branch of the local SAFE office and the branch of the People's Bank of China respectively.
8. Simplify cross-border RMB business procedures related to epidemic prevention and control. Banks are encouraged to directly handle cross-border RMB settlement business related to epidemic prevention and control, as well as domestic payment and use of RMB income under capital account, on the basis of payment and receipt instructions submitted by enterprises.
9. As of March 31, the imported materials directly used for epidemic prevention and control organized by the competent health authorities were exempted from customs duties, and the customs duties already collected shall be returned.

V. Others

1. Individuals are exempt from individual income tax by obtaining government standard grants and bonuses for temporary work in epidemic prevention and control.
2. Medical protective articles issued by an individual to prevent novel coronavirus from contracting pneumonia are exempted from individual income tax.
3. The cash and articles donated by public welfare social organizations or the people's governments at or above the county level and their departments to cope with the epidemic situation are allowed to be fully deducted from the enterprise income tax or individual income tax.
4. Donations of outbreak supplies directly to hospitals that are responsible for epidemic prevention and control are fully deductible from corporate or personal income tax.
5. Free donation of epidemic goods are exempted from value-added tax, consumption tax, city maintenance and construction tax, education fee surcharge, local education surcharge.

The above summarizes the national provisions applicable to the enterprises in China. It is important to note that local governments also offer more specific assistances to different local businesses. Policies in different provinces and cities have different regulations on the scope and ways of assistance to enterprises. At the same time, the central government has delegated the power to set some detailed rules to local governments during the epidemic period. Many local governments have provided more assistance to small and medium-sized enterprises and local enterprises.

Contact Us

Grandway Law Offices (Shanghai)
www.grandwaylaw.com

23F, S2 Building, Bund Financial Center, 600
Zhongshan No. 2 Road (E), Shanghai, 200010,
China

