



## China Commercial Regulatory Summary

July - December 2020

A semi-annual summary of the key Chinese policies affecting UK business

*This product aims to inform new and expanding UK businesses selling to or located in China about the commercial regulatory issues most likely to affect them. We are providing factual information rather than analysis. All feedback welcome.*

### Summary:

H2 2020 was a busy period for China's legislation: we saw the publishing of a batch of important (draft) laws and regulations in areas ranging from IP, standards, and anti-monopoly, to finance, cyber, and government procurement. Despite vowing to continue opening up amid concerns around "dual circulation", China has implemented stricter export controls, renewed foreign investment screening, sanctions blocking regulations as well as tightened COVID-related customs scrutiny. At a sector level, positive trends in pharma and education continue, and the "green" concept has become a repeated theme across sectors (esp. finance, auto, energy and environment).

With the signing of [Regional Comprehensive Economic Partnership \(RCEP\)](#) and [EU-China Comprehensive Agreement on Investment \(CAI\)](#), China progressed on strengthening its geopolitical position over the same period.

### **CROSS-CUTTING POLICIES:**

With a focus on setting economic development goals for the next five years, the **5<sup>th</sup> Plenum of the 19<sup>th</sup> Communist Party of China (CPC) Central Committee** was held from 26 to 29 October, 2020. Amid concerns around the heavy domestic focus of 'dual circulation', China committed to "raise the level of openness to the outside world" and "promote the liberalisation and facilitation of trade and investment". In particular, China pledged to enhance international cooperation on science and technology, and establish a global scientific research fund. Read the [Communique](#) of the plenum ([CN](#)), a record of the press conference ([CN](#)), and a summary of key takeaways ([EN](#)).

On 21 July, China released the **Measures on Further Improving the Business Environment**, adding clearer steps for the implementation of business environment reforms and bringing new opportunities via calls to open up government data to the public and encourage the development of digital health. Read the Measures ([CN](#)) and a summary ([EN](#)).

China published **draft Data Security Law (DSL)** in July and **draft Personal Information Protection Law (PIPL)** in October. The draft DSL highlights that a data security review mechanism will be introduced to assess the potential risks data pose to national security and public interest. 'Critical data' will certainly receive stricter scrutiny although its definition remains vague. The draft PIPL provides broad definition of 'sensitive personal information' and for the first time expands the scope to cover the processing out of China of personal information related to individuals in China. These two laws are expected to complement China's Cybersecurity Law in providing the country's legislative framework for data security. Read the draft DSL ([CN/EN](#)) and a media summary ([EN](#)); the draft PIPL ([CN/EN](#)) and a commentary ([EN](#)).

On 14 August, China's Ministry of Justice released **draft proposals to strengthen the Protection of Trade Secrets and Confidential Business Information in Administrative Licensing**. It requires that trade secrets and confidential business information acquired by an administrative licensing authority should only be accessed on a need-to-know basis and must be desensitized if the information needs to be shared. Read the proposal ([CN](#)) and a summary ([EN](#)).

On 28 August MOFCOM and the Ministry of Science and Technology jointly issued the **Revised Catalogue of Technologies Prohibited and Restricted from Export**, adding new technologies in areas such as personalised information push service based on data analysis, aerospace bearing, unmanned aerial vehicle and laser. Read the Catalogue ([CN](#)) and a media summary ([EN](#)).

On 31 August, China's Ministry of Commerce (MOFCOM) announced **a new foreign investor complaints mechanism** to deal with grievances against government officials. For the first time foreign businesses, chambers and associations are allowed to raise concerns / suggestions relating to China's investment environment. Read the announcement ([CN](#)) and some in-depth analysis ([EN](#)).

On 19 September MOFCOM published the **Provisions on the Unreliable Entity List**, outlining actions that could get an entity placed on the list, investigative processes and determinations, punishments, as well as how an entity might apply to get itself off the list. The actual list was still not released. Read the Provisions ([CN](#)) and a media summary ([EN](#)).

On 17 October, China passed its first **Export Control Law**, effective from 1 December. This law applies to goods, services and technologies (including related data) covering 1) dual-use items, 2) military products, 3) nuclear and 4) all others related to 'safeguarding national security and interests and fulfilling international obligations such as non-proliferation'. This Law has come into force since December. Read the Law ([CN](#)) and some legal analysis ([EN](#)).

On 17 October, China's legislature National People's Congress (NPC) passed the **amended Patent Law**, effective from 1 June 2021. The new law brings significant change to the pharmaceutical sector through introducing patent term compensation for a maximum of 5 years, and most importantly, a patent linkage system, which provides a communication mechanism between the national drug regulator and the patent office to prevent premature entry of generic drugs. Read full text ([CN/EN](#)), and more analysis into the patent linkage system in the DEEPDIVE section.

On 7 December China's Ministry of Finance released **draft Amendments to its Government Procurement Law**, strengthening its commitment to non-discrimination yet retained the domestic preference clause. For the first time, it includes a reference to 'other procuring entities' as entities that could conduct procurement projects. However it remains unclear what entities will fall into this category. Read the draft Amendments ([CN](#)) and some in-depth analysis ([EN](#)).

On 11 November, the NPC approved amendments to the **Copyright Law**, effective from 1 June 2021. The new law provides punitive damages for intentional infringement worth up to five times the determined damages. The amendment also increases the range of statutory damages from a maximum of RMB 500,000 to between RMB 500 and 5 million, to be awarded when the damages cannot otherwise be determined. More here ([CN](#)) and a commentary ([EN](#)).

On 15 November China signed the **RCEP** with [14](#) other Asia-Pacific countries. Specifically tariffs on industrial goods imports from Japan will be cut by 86%. On 30 December, China and the EU agreed the **CAI**, adding new language on environment and labour standards, technology transfer, state-owned enterprises and subsidies, as well as new sectorial opportunities including in financial services and healthcare. Read RCEP text ([CN/EN](#)), some chapters of CAI ([EN](#)) and a commentary ([EN](#)).

On 19 December, China formally introduced a new **foreign investment screening regime**, effective from 1 January 2021. The range of sectors where investments might be submitted for screening is broad, covering new 'greenfield' investment as well as acquisitions. Investments from Hong Kong, Macau and Taiwan are all in scope as well as 'foreign' investment. Read the full text ([CN](#)), a Q&A on the regime ([CN](#)) and a media report ([EN](#)).

On 19 December China's State Administration for Market Regulation (SAMR) issued **draft Administrative Measures for National Standards**, committing to actively adopting international standards and accelerate the conversion / application of international standards. Open, transparent and wide-reaching consultation periods will be included when developing new standards. Read the draft Measures ([CN](#)).

In December, China consecutively published a new **Market Access Negative List** ([CN/EN](#)), a new **Encouraged Foreign Investment List** ([CN/EN](#)) and a **Hainan-specific Foreign Investment Negative List** ([CN/EN](#)). In particular, foreign companies in Hainan are now allowed to establish wholly foreign-owned enterprises (WFOEs) to operate Online Data Processing and Transaction Processing Services, and to manufacture passenger vehicles.

On 9 January, MOFCOM issued **Rules on counteracting unjustified extra-territorial application of foreign legislation and other measures**, effective immediately. The rules provide a process for Chinese authorities to 1) issue prohibitions to reject the extra-territorial application of other countries' sanctions measures; 2) provide support for Chinese entities disadvantaged by the third-country application of overseas sanctions polices; and 3) take 'counter measures' against countries that apply them. Read the rules ([CN/EN](#)), a Q&A session ([CN](#)) and some in-depth analysis ([EN](#)).

## **SECTORS:**

### **AGRICULTURE**

On 11 September the General Administration of Customs of China introduced '**circuit breakers' mechanism for foreign manufacturers with SARS-COV-2 positive consignments**, effective immediately. According to this mechanism, Customs will suspend the import declaration of the foreign manufacturer for one week, if their products are tested positive for SARS-COV-2 nucleic acids for the first and second time, and for four weeks if their products are tested positive for the third time and more. The import declaration will automatically resume after the suspension period. Read the announcement ([CN](#)).

On 22 October China's National Health Commission introduced **stricter scrutiny over cold chain food** among rising concerns that contaminated cold chain food has a role to play in spreading the virus. Read the announcement ([CN](#)).

### **FINANCE**

On 08 July, the People's Bank of China (PBOC), the China Securities Regulatory Commission (CSRC) and NDRC released **draft Green bond Endorsed Projects Catalogue (2020 Edition)**. 'Clean' fossil fuels (incl.coal) have been removed from the Catalogue. Read the announcement ([CN/EN](#)) and a commentary ([EN](#)).

On 16 October, PBOC issued draft Amendments to China's **Commercial Banking Law**, enhancing corporate governance and risk management for domestic lenders. The Law defines 'legal behaviours' during companies' reorganisation/takeover/bankruptcy, and will allow Chinese regulators to prosecute unlicensed foreign institutions providing services in China. Read the draft Law ([CN](#)) and a media summary ([EN](#)).

On 23 October, PBOC published **draft People's Bank of China Law**, providing regulatory framework and legitimacy for a forthcoming central bank digital currency, the digital yuan. The draft law strengthens financial macro-controls and the professional duties of PBOC, and calls for a “twin pillar” regulatory framework comprised of monetary and macro-prudential policy. Read the draft Law ([CN](#)) and a commentary ([EN](#)).

## TECHNOLOGY

On 7 September, China released a **Guideline on Deepening Beijing's Service Industry Expansion and Opening**. It pledges to reduce foreign shareholding limits for Domestic IP-VPN services and Information Services Business (also known as Internet Content Provider “ICP”). This was followed by the announcement on 21 September that Beijing will build its own free trade zone (FTZ) with tech innovation as one key theme. Read the Guideline ([CN](#)), Beijing FTZ Development Plan ([CN](#)) and a commentary ([CN](#)).

## HEALTHCARE AND PHARMACEUTICALS

On 11 December, the National Medical Products Administration released the **Administrative Measures for Approving Biological Products**, effective from 1 March 2021. According to the Measures, vaccines urgently needed to prevent infectious disease can be exempted from the standard 60-day approval process. Following the announcement, China has already [granted](#) conditional approval for Sinopharm's COVID-19 vaccines. Read the Measures ([CN](#)).

On 28 December, China published new **National Reimbursement Drug List**, adding 119 new drugs after 51% price cuts. The new list covers 2,800 drugs including some antiviral drugs (e.g. Arbidol, Ribavirin) for treating COVID-19. The list will take effect from 1 March 2021. Read the announcement ([CN](#)) and a summary ([EN](#)).

## ENERGY

On 27 August 2020, the National Development and Reform Commission (NDRC) and the National Energy Administration jointly issued a **guideline on integrating various power sources with an aim to increase the utilisation of clean energy**. Read the guideline ([CN](#)).

On the 21 December China released the **White Paper of Chinese Energy Development in the New Era**. The Paper sets out China's major policies and initiatives to promote energy reformation, as well as how the energy sector will contribute to the goal of peaking emissions before 2030. Read the Paper ([CN](#)) and a media report ([EN](#)).

## E-COMMERCE

On 20 October, the SAMR released **draft Administrative Measures for Regulating Online Transactions**. Online platforms will be required to notify consumers of any ongoing infringement disputes on their platforms by publicising information on the store's homepage. Read the draft Measures ([CN](#)).

On 10 November, the SAMR sets out **draft guidance on stricter anti-monopoly rules for its online platform giants**. Merger and acquisition cases involving companies with a [variable interest entity \(VIE\)](#) structure, which most Chinese Internet platform companies adopt, will be subject to the government's anti-monopoly review. And for the first time tying sales algorithmic price discrimination and forcing users to choose platforms are defined as behaviour of abuse use of dominant market position. During China's annual Central Economic Work Conference, **'enhancing anti-trust efforts and preventing disorderly capital expansion' has been listed as one key task for the government in 2021**. Both Alibaba, Tencent have been [fined](#) for their monopolistic behaviours. Read the draft guidance ([CN](#)) and a media summary ([EN](#)).

## AUTO

On 11<sup>th</sup> August, the NDRC published **draft Interim Administrative Measures for the Remanufacturing of Motor Vehicle Parts**. The Draft Measures aim to further regulate auto parts remanufacturing, guarantee the quality of remanufactured products, and accelerate the standardised and large-scale development of the remanufacturing industry. Read the announcement ([CN](#)).

On 2 November China unveiled the **New Energy Vehicle Industry Development Plan (2021 – 2035)**, setting out target for new energy vehicle sales to account for 20% of China's auto market by 2025. Read the announcement ([CN](#)) and a media summary ([EN](#)).

## ENVIRONMENT

On 15<sup>th</sup> December, the Ministry for Ecology and Environment released the **Administrative Measures for Ecological and Environmental Standards** ([CN](#)).

## **EDUCATION, SKILLS AND SPORTS**

Since September 2020 China issued **a series of guidelines to facilitate the integration of sports and arts education into China's academic education system**. Physical and aesthetic exercise scores will be counted in China's National College Entrance Examination (Gaokao). Read the guidelines ([CN](#)) and ([CN](#)), as well as a summary ([EN](#)).

On 7 December China's Minister of Education when speaking at the International AI and Education Conference **called for more opening in the education sector**, emphasising the importance of developing online education and bringing in more high-quality educational resources to China. Read key messages of the speech ([CN](#)) and ([EN](#)).

## **POLICY DEEPDIVE**

### **China to establish an Early Resolution Mechanism for Pharmaceutical Patent Disputes**

On 11 September, China's drug regulator, the National Medical Products Administration (NMPA) and patent administration, China National Intellectual Property Administration (CNIPA) jointly issued the draft Implementation Measures for the Early Resolution Mechanism for Pharmaceutical Patent Disputes. It is regarded as China's latest attempt to provide a 'patent linkage system', which is highly advocated by the US. UK does not implement such a system. However, if the patent linkage is implemented in China, UK pharmaceutical innovators can potentially benefit from it by preventing infringing generics entering the market too early (so-called "pre-mature registration"). Generic drug manufacturers can also avoid patent infringement suits at early stage.

#### **What China's patent linkage system will look like?**

Patent linkage refers to the communication between the national drug regulator and the patent office to prevent marketing approval of generic drugs until after the expiration of patents covering the drug product. Currently, potential patent infringement is not a consideration when the NMPA examines an application for marketing authorization in China.

The draft Measures require that when a new drug application is filed, applicants must provide a "Patent Statement" to declare that the drug being applied for will not infringe any existing patent recorded on the Patent Information Platform for Marketed Drug maintained by NMPA. If a patent holder disagrees and believes the technical solution of the new drug applying for market approval will infringe their patent, they can either file a lawsuit in court or apply to the patent administrations for an administrative ruling within 45 days of the publication of the generic application. The NMPA will then halt the administrative approval process for 9 months to wait for a court decision or an administrative ruling.

#### **What does it mean for UK pharmaceutical industry?**

With the patent linkage system established, innovative drug developers in the UK will have further opportunity to secure legal exclusivity without worrying about the premature market entry of a generic competitor, which further secures a return on their R&D investment. In view of the upcoming patent linkage system, original drug innovators should make necessary preparation. More specifically, it is recommended to carefully review their patent portfolio and register the patents in NMPA's marketed drug patent information system, closely monitor market approval applications of generics and prepare challenging document, and be prepared for a surge of patent invalidation actions.

For more information please contact Leo Zhuang, Intellectual Property Officer at the British Embassy in Beijing:  
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## **IEW FROM THE BUSINESS COMMUNITY:**

**On 8 December the British Chamber of Commerce in China released its [annual sentiment survey](#)**. The survey revealed that British businesses are broadly optimistic about the outlook in China and highlighted growing business concern about the UK-China bilateral relationship. Despite the opportunities China presents for business, significant barriers remain. Top challenges listed were consistent with last year: cybersecurity and IT restrictions, repatriating capital, and competing with Chinese State-Owned Enterprises. Covid-related travel restrictions were also making employing foreign staff harder.

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