瑞士文斐律师事务所
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I. Provisions on Facilitating and Regulating Cross-border Data Flow

On March 22, 2024, six months after the release of the "Draft Regulations for Standardizing and Promoting Cross-Border Data Flow" (hereinafter referred to as "the Draft"), the Cyberspace Administration of China （"CAC"） officially issued the "Regulations for Promoting and Standardizing Cross-Border Data Flow" ("the Regulation") which took effect on the same day. This marked a further clarification and refinement of the compliance and exemption pathways for enterprises' cross-border data transfers. In this issue of CLB, we focus on introducing the background, content, and its impact on the compliance responsibilities and strategies of foreign-invested enterprises (FIEs).

- Background

As we analysed in our China Legal Report (October 2023), before the official introduction and implementation of the Regulation, the legal framework outlined three compliance pathways for cross-border data transfer: conducting a data export security assessment, establishing and filing a standard contract for personal information export, and obtaining personal information protection certification ("the Three Pathways"), without specifying any exemption scenarios and the corresponding conditions to be met for exemptions. Thus, any enterprise involved in cross-border data transfer, regardless of industry nature and data volume, had certain level of compliance obligations. The minimum compliance requirement involved signing a standard contract with the overseas data recipient and filing it with the CAC before November 30, 2023. Although the Draft issued on September 28, 2023, had specified several exemption scenarios from the Three Pathways, its final version, i.e. the Regulation was not released until March 22, 2024. Consequently, many enterprises, albeit having met the exemption scenarios outlined

in the Draft, still opted to establish and file standard contracts due to compliance risk considerations. The final implementation of this Regulation in March this year clearly defined the scenarios and conditions for exemption from the Three Pathways, facilitating enterprises to reasonably evaluate and plan their cross-border data transfer strategies and compliance strategies.

Compared to the Draft, the finally released Regulation focuses more on "promoting" rather than "regulating," not only in the title but also in the content. It expands the exemption scope for cross-border data transfer, relaxes restrictions on non-critical data cross-border transfer and improves the guidance and validity for data export security assessment.

- Exemptions of the Three Pathways

The most important aspect of this regulation is the clear definition of exemption scenarios, significantly reducing the compliance costs for applicable enterprises:

The Regulation specifies the following scenarios where data export can be exempted from the Three Pathways.

1) Data collected and generated in activities such as international trade, cross-border transportation, academic cooperation, transnational production and manufacturing, and marketing provided overseas, excluding personal information or critical data. (Article 3)
2) Personal information collected and generated overseas by data processors transmitted back to China for processing and then provided overseas, without introducing domestic personal information or critical data. (Article 4)

3) For the establishment or execution of a contract where an individual is a party, such as cross-border shopping, mailing, remittance, payment, account opening, airline and hotel booking, visa application, and examination services, necessitating the provision of personal information overseas; Implementing cross-border human resources management in accordance with legally established labour regulations and legally signed collective contracts, necessitating the provision of employees' personal information overseas; In emergency situations to protect the life, health, and property safety of natural persons, necessitating the provision of personal information overseas; Data processors other than critical information infrastructure operators providing less than 100,000 individuals' personal information (excluding sensitive personal information) overseas cumulatively from January 1 of the current year. (Article 5)

4) Enterprises within the free trade pilot zones, whose data export are not listed in the "negative list" specified by the zone. (Article 6)

- Refining the Scope of Data Export Security Assessment.

Article 7 states that data processors providing data overseas, meeting any of the following conditions, should submit a data export security assessment to the CAC through the provincial-level cyberspace department:

-Critical information infrastructure operators providing personal information or critical data overseas;

-Non-critical information infrastructure operators providing critical data overseas, or cumulatively providing personal information to more than 1 million individuals (excluding sensitive personal information) or sensitive personal information to more

than 10,000 individuals on a cumulative basis starting from January 1 of the current year.

As shown on Paragraph 2 of Article 7 and in comparison to the Draft, the Regulations further restricted the export of sensitive personal information by adding the requirement for a data security assessment when non-critical information infrastructure operators transfer sensitive personal information of more than 10,000 individuals overseas.

- Extending the Validity Period of Security Assessments

Article 9 extends the validity period of data export security assessments from two years to three years. If an enterprise needs to continue data export activities without circumstances necessitating a redeclaration for a data export security assessment before the expiry, it can apply for an extension of the assessment result's validity period with the CAC through the provincial-level cyberspace department 60 working days before expiry. Upon approval by the CAC, the validity period can be extended by three years. This significantly reduces the compliance costs for enterprises whose validity period is about to expire.

- Recommendations:

Based on our experience, FIEs usually involve in cross-data transfer, therefore should keep monitoring and analysing the types and flow of data involved in their operations in China, assessing and planning their cross-border data transfers in a compliant way. Based on business characteristics, FIEs shall optimize data collection, storage, usage, and transmission processes, and if possible, apply exemption scenarios. If exemption scenarios are not met, they should promptly determine the applicable cross-border data transfer pathway according to the Regulation, communicate with regulatory authorities, and proceed with security assessment, contract filing or certification as soon as possible.

Even if enterprises meet specific exemption scenarios for cross-border data transfer, they still need to ensure the security and compliance of other routine data processing activities. This includes but is not limited to 1) fulfilling notification obligations and obtaining consent; 2) conducting self-assessment of the impact on personal information protection; 3) Additionally, even if there is no need to file with the CAC, enterprises can still sign standard contracts with overseas personal information recipients, requiring and restricting the overseas recipient's data processing activities to meet the protection standards under Chinese law through contractual means, and clarifying the rights and obligations of both parties.

II. Steadily Promoting High-level Opening up and Making Greater Efforts to Attract and Utilize Foreign Investment

On February 28, 2024, the General Office of the State Council of China issued the "Action Plan for Steadily Promoting High-level Opening up and Making Greater Efforts to Attract and Utilize Foreign Investment" (hereinafter referred to as the "Action Plan"). The aim is to consolidate the confidence of foreign-invested enterprises in China and to improve the quality and level of trade and investment cooperation. Below is a summary of several key points of the Action Plan:

- Further Expand Market Access

This expansion primarily focuses on loosening restrictions on foreign investment in the field of technological innovation, expanding market access for foreign financial institutions in the banking and insurance sectors, broadening the permitted scope of foreign financial institutions participating in the domestic bond market business, and deepening the implementation of pilot projects for qualified overseas limited partners

investing domestically.

- Improve Relevant Specific Policies

Firstly, in the closely watched area of tax policies, foreign-invested enterprises reinvesting in projects they have previously invested in China, and meeting the conditions stipulated in the Catalogue of Industries Encouraging Foreign Investment, may enjoy the policy of duty-free import of self-use equipment as prescribed. Additionally, financial institutions are encouraged to provide high-quality financial services and financing support to eligible foreign-funded projects in accordance with market principles. Meanwhile, there are plans to consolidate and develop key development zones in the central-western and northeastern regions, pairing them with zones in the eastern region to facilitate cooperation in the transfer of foreign investment industries.

- Strictly Address Cases Violating Fair Competition

To optimize the environment for fair competition and better serve foreign-invested enterprises, the Chinese government strictly implements the administrative law enforcement public notification system to promptly correct irregular administrative enforcement actions. It is also necessary to promptly address discriminatory practices against foreign-invested enterprises reported by business entities in government procurement, bidding, qualification licensing, standard-setting, subsidy enjoyment, and other aspects.

- Encourage Innovation and Promote Cooperation between China and Foreign Countries

To further strengthen cooperation, the Action Plan requires standardizing the management of cross-border data security. It organizes and conducts assessments of data exiting the country,

standardizes contract filing for the exit of personal information, and promotes the orderly flow of cross-border data security in research and development, production, and sales for foreign-invested enterprises. To facilitate visa applications for foreigners coming to China, the validity period for visas for management personnel, technical staff, and their accompanying spouses and minor children of foreign-invested enterprises is extended to two years, further improving the management of work and residence permits for foreigners in China.

- Conclusion

This Action Plan reflects the Chinese government's aim for greater openness and inclusivity, promising a relaxed and scientifically structured business environment in the future. For more comprehensive policy consultation, please feel free to contact Wenfei.

III. Good Supply Practices for Medical Devices

On December 4,2023, the *Good Supply Practices for Medical Devices* ("**the Practices**") was released by the PRC National Medical Products Administration Authority and will take effect on July 1, 2024. Compared with the old 2014 version, the Practices has been modified a lot. In this publication, we will briefly introduce some key content of the Practices.

- Newly added chapter "Establishment and Improvement of the Quality Management System"

According to this chapter, the enterprise shall establish a sound quality management system, which includes documents, organizations, personnel, facilities and devices, etc. Additionally, an enterprise distributing medical devices of Class II and Class III shall conduct self-inspection and submit a report for the previous year to the local

medicinal product regulatory department before March 31 each year. The content of a self-inspection report shall be authentic, accurate, integral and retrospective.

- Summary of the Practices requiring enterprises to make relevant records

Article 25 of the Practices stipulates that the person responsible for quality control and management shall be on duty. Enterprises shall record the appointment, adjustment, and performance of responsibilities of such personnel and file the record for future reference. Article 64 of Practices changes the acceptance record to the inspection record. The personnel shall check and verify the exterior appearance, packages, labels, and qualification certificates of the medical devices delivered and keep proper inspection records of the purchase. Article 77 provides that an enterprise shall periodically take inventory of the medical device, and if the enterprise discovers any quality or quantity problems, it shall promptly investigate the causes and keep records. Article 83 stipulates that operating enterprises engaging in wholesale business of Class II and Class III medical devices and retail business of Class III medical devices shall implement a sales record system.

- Mixing storage of Non-Medical Devices and Medical Devices

It’s made clear in Article 43 of the Practices that if non-medical devices and medical devices are stored in a warehouse, the warehouse shall be effectively managed in different areas. Enterprises shall fully evaluate the risk of pollution caused by non-medical devices to the storage environment and personnel and take measures to ensure the safe environment for medical devices.

- Conclusion

Since the Practices release in 2023, it has played a positive role in regulating the business conduct of medical devices, strengthening the quality supervision of medical device business, promoting the standardised development of the industry, and safeguarding the safety and effectiveness of public use of devices. Medical devices related enterprises should pay more attention to the Practices and ensure a timely compliance. For more detailed enquiries, welcome reach Wenfei law.

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