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1. Unreliable Entity List Regime will be released soon

On May 31, 2019, The Ministry of Commerce of China (MOFCOM) announced that the Chinese government will introduce an "Unreliable Entity List" regime. According tothe new regime, any foreign entities or individuals that boycott or cut off supplies to Chinese companies for non-commercial purposes causing serious damage to Chinese companies will be listed as "Unreliable Entities". The detailed rules, including the list itself and the restrictive measures applicable to the listed entities, will be separately released in the near future.

The MOFCOM officials commented that whether an entity will be listed as unreliabledepends on the following four factors: (i)whether or not the entity has taken "discriminatory measures" against Chinese companies, such as boycotting or cutting off supplies, (ii) whether or not these measures are taken for non-commercial purposes and are against market rules and contractual obligations, (iii) whether or not the actions cause material damage to Chinese companies and the related industries, and (iv) whether or not the action poses apotential threat to China's national security.

Once an entity is listed as “Unreliable Entity”, it will have to bear legal responsibility according to the Foreign Trade Law, Antitrust Law, National Security Law and others.

However, it is really unpredictable whether an entity will be listed as or not,since no detailed rules have been released yet. Further, it is not clear if subsidiaries of foreign companies in China might also be listed because of similar reasons stated above.

2. Measures for Security Assessment for Cross-border Transfer of Personal Information (Draft for Comment)

On June 13, 2019, the Cyberspace Administration of China (CAC) published a second draft of the Measures on Security Assessment for Export of Personal Information (Second Draft Measures).The Second Draft Measures wereopen for public comment until July 13, 2019. According to the Second Draft

Measures,network operators will have to apply for assessment on the security of the information before transferring information abroad. The assessment procedure is as follows:

(1) Application Procedure

Beforetransferring certain information abroad, network operators have to apply forthe approval ofthe provincial cyberspace administration that has jurisdiction for security assessment for cross-border transfers of certain information. The following materials have to be submitted: application form, contracts,analysis report on security risks and security guarantee measures with regard to cross-border transfer of personal information and other materials required by the national cyberspace administration.

(2) Assessment procedure

The cyberspace administration will assess the materials and focus on the following aspects:

- Whether or not the information transfer complies with the provisions of relevant national laws, regulations and policies;
- Whether or not the terms of the contracts can fully protect the legitimate rights and interests of the subjects of personal information;
- Whether or not the contracts can be effectively implemented;
- Whether or not network operators or recipients have a record of damaging the legitimate rights and interests of the subjects of personal information, and whether major network security incidents have occurred to them.

The Second Draft Measures also require network operators to report the situations of cross-border transfer of personal information and contract performance to the local cyberspace administrations every year. The CAC recommends that Network Operators formulate corresponding systems to comply with the expected new law.

Obviously, the Second Draft Measuresstrengthen the control of network operators by the national network security management department andallows the CAC absolute controloverinformation flows to the outside world.This is none

the least due to the fact that the law is formulated very openly and its field of application, at the time given, remains relatively unclear.

3. Directory of Activity Sectors, Project Catalog and List of Industrial Supervisory Authorities for Foreign Nongovernmental Organizations

On April 29, 2019, the Ministry of Public Security of the People's Republic of China (the "Ministry of Public Security") published its Directory of Activity Sectors, Project Catalog, and List of Industrial Supervisory Authorities for Foreign Nongovernmental Organizations (2019) ("2019 Directory").

According to article 11 and 34 of the Law on Administration of Domestic Activities of Overseas Non-government Organizations in China, overseas Nongovernmental Organizations (NGOs) applying for registration and establishment of a representative office need to obtain consent from the supervising authorities.Afterobtaining the approval from such competent industrial supervisory authority, the NGO may then file an application to register a China office at a provincial public security bureau.

It may bedifficult for foreign NGOs to find a supervising authority that is needed for foreign NGOsto start operations in China. The 2019 Directory nowlists the supervising authorities in a more detailed way, which might help overseas NGOs to find the corresponding business supervisors more quickly.

Supervising authorities for foreign NGOs are divided into the following areas: Economics, Education, Science and Technology, Culture, Health, Sports, Environmental Protection, Poverty Alleviation and Disaster Relief and other industries.

4. Administration Measures on Medical Consumable Supplies

On June 6, 2019, The State Health Commission published the Tentative Administration Measures on Medical Supplies (Measures). The Measures will be effective on September 1, 2019.

The main content of the Measures is as follows:

(1) Definition of Medical Consumable Supplies

The "Measures" clarify the definition and classification of medical consumable supplies. According to article 2 of the Measures, medical consumable supplies refers to consumable medical devices that have been approval by the drug regulatory authority and have limitation on times of usage, including disposable and reusable devices.

(2) SupplierCatalog of Medical Consumable Supplies

Medical institutions are required to formulate a supplier catalogue of medical consumables for their institutions. Medical institutions are required to limit the number of medical consumable supplies. At the same time, the number of suppliers for medical consumables with the same or similar functions is limited.In addition, the procedure has to be independently conducted by special personnel. Departments andpeople other than the purchasing department areprohibited from engaging in procurement. In addition, they are also prohibited from using medical consumable supplies which are purchased by the non-purchasing department.

(3) Establishmentofahierarchical management system for the clinical use of medical consumables

The clinical use of medical consumables is classified in three levels according to the National Medical Supervision Administration's Catalogue of Medical Devices (the catalogue divides medical devices into categories I, II, and III). Class I of medical consumables is used by health technicians; Class II is used by qualified health technicians after relevant training; Class III medical consumables are in accordance with medical technology management regulations and are subject to relevant technical operation qualifications used by qualified personnel.

(4) Information System

Medical institutions are required to establish medical consumables information systems, which includesthe selection, procurement, acceptance, storage, inventory, application, delivery, clinical use, quality and safety incident reports, adverse reaction monitoring, key monitoring as well as abnormal warning, in order to tracethe entire life cycle of each medical consumable.

(5) Punishment

The Measures state that the violation of relevant medical regulations will be published but no specific punitive measures were published at present.

As the Measureswill take effect soon,the State Health Commission recommends that medical units, in accordance with the provisions of this Law, formulate management policies in a timely manner and respond to inspections by the health administrative department.

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