DS NEWSLETTER savoir, faire
NEWSLETTER – LEGAL INFORMATIONS
PROPOSED BY DS AVOCATS

Online Sales of Medical Devices in China

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This is our fourth newsletter on the regulation of medical devices ("**MD**") in China, following the effectiveness of the Regulation on the Supervision and Administration of Medical Devices since June 1, 2021 ("**2021 Regulation**").

In this newsletter we will focus on online sales of MDs and see what the regulatory requirements under the 2021 Regulation are. Indeed, the on-line distribution model of MD ("Internet plus MD") developed under the impact of Covid-19; therefore, it is crucial for companies involved in the business operations of MD to master the regulatory framework of online sales.

Before the 2021 Regulation, the National Medical Product Administration ("**NMPA**"), formerly the *China Food and Drug Administration* ("CFDA"), promulgated Measures for the Administration and Supervision of Online Sales of Medical Devices in the end of 2017 ("**Measures**"). These Measures set general rules of regulatory requirements for entities engaging in online sales of MD and specified liabilities for any breach of such Measures. Based on the Measures, the 2021 Regulation newly incorporates the concept of online sales of MDs at the level of the State Council, which is the highest administrative authority in China.

REGULATORY REQUIREMENTS FOR MD COMPANIES

The 2021 Regulation allows a MD Registrant/Filer or a MD business operator (together, "**MD Company**") to engage in online sales of MDs. An MD Company can carry out online sales of MDs either via its own website or via a third-party platform which provides online trading service for MDs.

What are the regulatory requirements for MD companies engaging in online sales?

(1) Operations conducted by MD Registrant/Filer: Where a MD Registrant/Filer operates the MD registered and filed by it, it is not required to handle licensing or record-filing for business operation of MDs.
(2) MD Business Operating License/Filing. There is no need to apply for any business operating license/filing for sales of Class I MDs. For sales of Class II MDs, a business operator will need to file for record. For sales of Class III MDs, the business operator will need to obtain MD business operating license. This requirement applies regardless of sales via its own website or sales via third-party platform.
(3) Qualification Certificate for Medicine Information Services. An MD Company carrying out online trading services via its own website shall obtain the Qualification Certificate for Medicine Information Services on the Internet. This requirement is not applicable to sales via third-party platform.
(4) Information Filing for Online Sales of MDs. An MD Company is required to fill in the table of information of online sales of MDs and file relevant information with the local authorities (with which the MD Company is registered) for record. This requirement applies regardless of sales via its own website or sales via third-party platform.
(5) ICP Filing. An MD Company will need to make ICP filings for online sales via its own website (applications and mini-programs excluded). However, this does not apply to sales via third-party platforms as second-level domains are not subject to independent ICP filing.
(6) Business License. Applicable to online sales via its own website or via third-party platform, the MD Company will need to make sure such activities are covered in its business scope.

Besides such basic regulatory requirements, MD companies will need to comply with below:

- take technical measures to guarantee that data and materials in respect of online sales of MDs are authentic, complete and traceable;
- actively cooperate with authorities in network monitoring, sampling inspection and on-site inspection, store data as required, and provide information inquiry, data extraction and other related support;
- keep records of the sales information of MDs and such records shall be kept till two years after the useful life of the MDs, or be kept for no less than five years in case of no useful life, or be kept permanently in case of transplanted MDs. The related records shall be authentic, complete and traceable.

LIABILITIES FOR BREACH OF MD REGULATORY REQUIREMENTS

(1) Liabilities of MD Companies. For MD companies engaging in online sales without suitable licenses, making timely changes of registration, or establishing and implementing management rules, the MD Company can be ordered to rectify or subject to an administrative fine (in worst case scenario, amounting to 20 times of the goods value of MDs that are illegally sold)[1].

(2) Liabilities of Responsible Persons. In case of MD quality safety problem, failure to handle MD quality complaint or failure to take measures to identify and eliminate MD quality safety hazards, the local authorities (with which the MD Company is registered) can decide to have regulatory talks with its legal representative or main responsible person. And if the MD company refuses to implement the decision on suspension of online sales or the rendering of the related online trading service, or that the MD company refuses to make rectifications as required after regulatory talks, the legal representative or main responsible person of such MD company can be added into the list of companies and persons acting in bad faith[2].

(3) Other Liabilities beyond the 2021 Regulation. For sales of non-compliant MDs, the MD Company can also be subject to relevant criminal and civil liabilities.

INCONSISTENCIES BETWEEN THE 2021 REGULATIONS AND THE MEASURES

It is worth noting that there is certain inconsistency between the 2021 Regulation and the Measures. For example, the Measures allow an MD Registrant/Filer, an MD manufacturing company or an MD business operator to engage in online sales of MDs; while the 2021 Regulation does not mention the possibility for MD manufacturing companies to sell online: as a result, if the manufacturing of MD is entrusted by MD Registrant/Filer to a third party, this would mean that the latter cannot sell the MD online; furthermore, the Measures provides that MD Company engaged in online sales of MDs should file with the regulatory authorities, while the 2021 Regulation provides an exception for the Class I MD operating companies and Class II operating companies specified in Paragraph 2 of Article 41 (with an exempt of operation filing).

Considering the Measures was introduced earlier, and that the 2021 Regulation is a superior law, it is likely that the authorities will make revisions to the Measures based on the 2021 Regulation. We will keep a close eye on this.

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1 Article 84 of the2021 Regulation provides that in case of any of the following circumstances, the MPA shall make public the names of the company and the products and order the company to make corrections within a prescribed time limit; if the company fails to make corrections within the prescribed time limit, the illegal gains and illegally produced or operated MDs shall be confiscated; if the goods value of illegally produced or operated MDs is less than RMB10,000, a fine between RMB10,000 and RMB50,000 shall be imposed on it; if the goods value is no less than RMB10,000, a fine between 5 times and 20 times of the goods value shall be imposed on it; if the case is serious, for the legal representative, principal, person directly in charge and other liable persons of the company that violates the law, the income obtained from the company during the period of the illegal act shall be confiscated, a fine of between 30% and 200% of the income obtained from the company shall be imposed on them, and they shall be prohibited from engaging in the production or operation of MDs within five years: (1) producing or operating Class I MDs that have not been filed for record; (2) engaging in the production of Class I MDs without filing for record; (3) engaging in the business operations of Class II MDs which shall be filed but failing to file for record; or (4) the materials that have been filed for record fail to meet the relevant requirements.

2 Liabilities of responsible persons are scattered in multiple Chinese laws and regulations. Mainly the persons on the bad faith list cannot act as legal representative, director, supervisor or senior management; such persons will also be prohibited from travelling by airplanes and taking soft sleepers on trains. He or she will be subject to restricted loans or credit cards with financial institutions and etc.

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