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

Medical Devices - Clinical Evaluation and Clinical Trials : Balance between Safety and Innovation before Marketing

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This newsletter is the second newsletter of our serie dedicated to Medical Devices Regulation in China further to the promulgation of the Regulations on Supervision and Administration of Medical Devices, which entered into force on June 1st, 2021 (the "**2021 Regulation**").

In this newsletter we will take a closer look at clinical evaluation and clinical trials.

The 2021 Regulations encourages through different measures, innovation and development of the medical device industry, Chinese regulators intending to maintain the delicate balance between safety and innovation in this area. The rules related to clinical evaluation and clinical trial for medical devices ("**MD**") are in this framework.

CLINICAL EVALUATION AND CLINICAL TRIALS – GENERAL FRAMEWORK

MDs in China are classified in three different categories based on their risk levels. Class I MDs refer to MDs with low risk, which safety and effectiveness can be ensured through routine administration. Class II MDs refer to MDs with medium risk under strict control and administration. Class III MDs refer to MDs with high risk under strict control and administration with special measures (such as surgical ultrasound system and disposable sterile aortic perforator).

Requirements for clinical evaluation and clinical trials vary depending on the classification type of the MD, and in this respect, 2021 Regulation brings some changes compared to the previous regulation dating back 2017 (the "**2017 Regulation**").

Generally speaking, the **2021 Regulation** specifies that clinical evaluation shall be conducted for product registration or record-filing of an MD, either by carrying out clinical trial, or by analyzing and evaluating the clinical literature and clinical data of the same variety of MDs. If the existing clinical literature and data are insufficient to confirm the safety and effectiveness of such MD during the clinical evaluation, clinical trials shall take place.

The 2021 Regulation further provides that clinical evaluation can be exempted under certain circumstances (see table below). On the other hand, theoretically, it could be possible that a clinical trial would be required for a class I MD.

(1) Clinical evaluation and clinical trials under 2017 Regulations

Risk Level	Clinical Evaluation	Clinical Trial
Class I	Required	N/A
Class II		Required, except for those under the catalogue of MDs that are exempt from clinical trials ("**Exempt Catalogue**")
Class III		

(2) Clinical evaluation and clinical trials under 2021 Regulations

Risk Level	Clinical Evaluation	Clinical Trial
Class I	Required, except for (1) the working mechanism is clear, design is finalized and production process is mature, the MD of the same variety on the market has been applied in clinical practice for years with no record of serious adverse event or the general purpose is not changed; or (2) such MD can be proved to be safe and effective through non-clinical evaluation.	Required, if the existing clinical literature and data are insufficient to confirm the safety and effectiveness of such MD during the clinical evaluation
Class II		
Class III		

With the 2021 Regulation the need for clinical evaluation or clinical trials is determined according to criteria that must be assessed and analyzed on a case-by-case basis. In some cases this may lead to an exemption from clinical evaluation and clinical trials.

APPROVALS AND FILINGS FOR CLINICAL TRIALS

(1) Approvals and filings for MD clinical trials

Clinical trials of MDs (with the exception of Class III MDs that have higher risks to the human body) must be conducted in qualified clinical trial institutions according to the requirements of the Good Clinical Practice ("**GCP**") for MDs and must be **filed** for record with the local office of the National Medical Products Administration ("**NMPA**"). On the other hand, clinical trials of Class III MDs with higher risks to the human body must be **approved** by the NMPA at national level.

(2) Implied permission for clinical trials for Class III MDs

Before approving a clinical trial for Class III MDs, the NMPA must comprehensively analyze relevant conditions[1], make a decision and notify the sponsor of the clinical trials within 60 working days after accepting the application. If the NMPA fails to notify the sponsor within 60 working days, it shall be deemed as consent.

The concept of implied permission for clinical trials already exists in the law for pharmaceuticals. It has been incorporated for MDs in other rules as promulgated by the NMPA since 2019. However, with the 2021 Regulation, the implied permission for clinical trials for MDs is officially established at highest level of administrative regulations.

(3) Procedural requirements for clinical trials

An ethical review must be conducted, and the subjects must be informed of the purpose, use, possible risks and other detailed information of such trial, and the written informed consent must be obtained from the subjects for clinical trials for MDs. If the subjects have no or limited capacity for civil conduct, a written informed consent must be obtained from their guardians. The clinical trials must be free of charge to the subjects.

[1] Relevant conditions generally include the equipment and professionals of the institutions to undertake the clinical trials, the degree of risks of the MDs, the implementation scheme, the comparative analysis report on the clinical benefits and risks.

EXTENDED CLINICAL TRIALS (EXPANDED COMPASSIONATE USE)

The 2021 Regulation incorporates the expanded compassionate use system for MDs in the administrative regulations of the State Council.

According to the principle of compassionate use, MDs under clinical trials can be used for patients other than those participating to the clinical trial. According to the 2021 Regulation, this expanded compassionate use is possible under several conditions:

- the compassionate use must take place within the institutions carrying out the clinical trials.
- the method of use of the MD for compassionate use must be consistent with the clinical trials in progress or completed,
- the scope of application of the MDs in the compassionate use must not exceed the scope of application confirmed by the clinical trials in progress or completed.

The applicant may submit the plan and date of such extended clinical trials for MDs for its product registration.

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We notice that since this May, the NMPA has solicited public opinions on the Model Clinical Trial Protocol for MDs and the GCP for MD Trials, and as of the date of this newsletter, the solicitation is over but the results not yet published. We will continue to follow the latest revisions on these rules.

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