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China Insight

Highlights on Recent Regulations on Customized Medical Devices

Dear Sir or Madam,

Please find below the highlights on recent regulations on customized medical devices.

Kind regards,
CMS, China

On 26 June 2019, the National Medical Products Administration ("NMPA") and the National Health Commission issued the *"Provisions on the Supervision and Administration of Customized Medical Devices (Trial)"* (the "Provisions"), which will be implemented from 1 January 2020.

The Provisions clarify the definition of customized medical devices and also stipulate that customized medical devices shall be subject to filing with authorities. The Provisions emphasize that both customized medical device manufacturers and medical institutions are obliged to make such filing. Also, the Provisions stipulate specific requirements for customized medical device manufacturers and medical institutions to use such devices.

1. Definition[1] of Customized Medical Devices

Article 31 of the Provisions provides that personalized medical devices can be divided into:

a) Customized medical device ("CMD"), which refers to the personalized medical device designed and manufactured by a medical device manufacturer according to the specific clinical requests of a medical institution in order to meet rare special lesions of a particular patient in the case that the current launched products available on the Chinese market are difficult to meet clinical demands of such particular patient. Such medical device is aimed at improving the effectiveness of diagnosis and treatment of such particular patient.

b) Patient matching medical device ("PMMD"), which refers to the personalized medical device designed and manufactured for a particular patient by a medical device manufacturer through a proven process based on standard specifications for mass production of medical devices, in accordance with the clinical demands. Common PMMDs are dentures, orthokeratology lens or orthopedic guide plates.

Compared with CMD, a PMMD is designed based on standardized products which have already obtained market authorization through the current registration/filing regime but with tailor-made adjustments to its models, whilst a CMD is designed to address a rare pathological condition of a particular patient and is in lack of enough samples to conduct clinical trials before production. The novelty and uniqueness of the characteristics of CMD make it difficult to be registered/filed through the existing registration/filing regime in China. As such, the

Provisions are formulated to regulate research and development, manufacturing and use activities in connection with CMD in China.

2. Scope of application

PMMDs are explicitly excluded from the Provisions, therefore, they should be registered or filed in accordance with the *Measures for Administration of Registration of Medical Devices* or the *Measures for Administration of Registration of In-Vitro Diagnostic Reagents*. Further, the Provisions stipulate that the following medical devices are not applied, respectively medical devices that meet the requirements of the *Procedures for Emergency Approval of Medical Devices*, or other CMDs containing pharmaceutical ingredients or bioactive components, such as cells and tissues.

3. Conditions of CMD Manufacturer and Medical Institution

The Provisions provide that a CMD manufacturer should meet the following conditions to produce a CMD:

- It has professionals and technical personnel required for the development and manufacture of such CMD;
- It has the capacity of research and development of such CMD;
- It has the medical device registration certificate for mass production in accordance with the standard specifications and corresponding production license to produce medical device in the same type as such CMD (overseas manufacturer shall hold the registration certificate issued by the competent authority of the medical device in the country or region where such manufacturer is incorporated or where the production site is located);
- It has the production capacity and experiences in mass production of medical device in the same type as such CMD in accordance with standard specifications and complying with respective quality management system.

A medical institution shall meet the following conditions to use a CMD:

- It has to be a Grade III comprehensive or Grade III specialized hospital with a medical treatment program that is compatible with the CMD to be used;
- It has a physician who is registered with a medical institution and is capable of using such CMD;
- It has experiences of using similar medical device which has already launched on the market, it has already carried out research and treatment with respect of same kind of disease and its clinical professional level is advanced in China;
- It has high level of medical device management skills, it has established a good and sound quality management system for using medical device and it has medical device use evaluation and medical device adverse event monitoring capabilities.

4. Regulatory Requirements

- Pre-marketing record-filing regime: Manufacturers and medical institutions of CMDs (collectively as the “Filing Applicant”) shall be jointly obliged to file record for each CMD on a case-by-case basis. Before producing and using any CMD, the Filing Applicant should file such CMD with drug supervision and administration department at the provincial, autonomous regional or municipal level where the CMD manufacturer is located (where such CMD will be imported, the location of the import agent shall apply here). This implies that a CMD can also be produced by an overseas CMD manufacturer. When a CMD manufacturer no longer holds the valid medical device registration certificate for mass production in accordance with the standard specifications or the production license, the filing of such CMD will automatically become invalid. The Filing Applicant shall take the initiative to cancel the filing record.
- Prohibition of contract manufacturing: From risk control perspective, the Provisions clearly state that CMD is strictly prohibited from being outsourced into contract manufacturing by CMD manufacturer.
- Prohibition of promotion: The Provisions stipulate that CMD must not be advertised or promoted through mass media.
- Design and manufacture: A manufacturer of CMD shall enter into an agreement with a medical institution who will use such CMD. The Provisions list out certain information (e.g. basic and registration information of the manufacturer and the medical institution, information of the patient and the attending doctor of such patient,

a statement on reasons for using such CMD and customized design, delivery and acceptance requirements of the CMD, etc.) which needs to be clarified in each and every order of CMD, and such information shall become part of the provisions of agreement between the manufacturer and the medical institution. In principle, the specifications and labels of CMDs shall comply with the requirements of the *Medical Device Specification and Label Management Regulations*, and the manufacturer shall also underline the customization of the CMD on such specifications and label, for instance, the name of a CMD shall have "customized" characters.

- Annual report: Different from the regular self-inspection reports required by the *Regulation on Supervision and Administration of Medical Devices*, both the manufacturer and the medical institution of CMDs are required to submit an annual report before the end of January each year to the regulatory authority and the annual report shall include information on the actual clinical use of the CMD by a particular patient.

- Traceability Mechanism: Medical institutions and manufacturers of CMDs need to ensure that each and every patient who uses a CMD can be traced throughout the whole process without jeopardizing such patient's personal information and privacy. According to the Provisions, manufacturers need to give a unique identification number for each CMD, and specify this number, the patient's name (identified by initials or a numeric code), the medical institution and the attending doctor in the specifications and label of such CMD.

- Record retention: The Filing Applicant is responsible for the maintenance and retention of CMD information. The retention period of relevant information associated with every CMD shall be no less than the life expectancy of such CMD specified by its manufacturer. The information in relation to the implantable CMD shall be stored permanently, whilst for other non-implanted CMDs, the information retention period shall be no less than 5 years from the date of release of such CMD by the manufacturer.

- Application for pre-marketing approval: The Provisions clarify that when the number of medical cases in which a type CMD is applied and the preliminary research meet the requirements for pre-marketing approval, the original Filing Applicant shall file for registration of or filing a record for such CMD in accordance with the provisions of the *Administrative Measures for the Registration of Medical Devices* and the *Administrative Measures for the Registration of In Vitro Diagnostic (IVD) Reagents*, so that it can become an ordinary medical device. Any authentic, accurate, complete and traceable clinical data of use which follows ethical codes can be used as clinical evaluation data for registration.

CMDs (such as artificial spine, joints and bone plates) have been used in practice by patients with special diseases over the recent years, yet there were no explicit provisions governing CMDs. The Provisions have undoubtedly filled the gap in the law with respect of CMDs in China. However, it is noticeable that the Provisions have only established a preliminary regulatory framework for CMDs, more detailed implementation rules (including ethical criteria for approving a CMD, CMD defects judgement, etc.) are expected to be issued in the future.

[1] As interpreted by NMPA on 4 July 2019 (http://www.nmpa.gov.cn/WS04/CL2201/338729.html), a personalized medical device refers to a medical device designed and manufactured by a medical device manufacturer according to the clinical requirements of an authorized medical professional of certain medical institution in order to meet demands of a particular patient. Personalized medical devices can be divided into two categories: customized medical devices and patient matching medical devices.

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