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China Amends its Regulation for Supervision and Administration of Medical Devices

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Food, Drugs, and Devices

On March 18, 2021, China's State Council released a significant revision of the framework regulation for medical devices, the Regulation for Supervision and Administration of Medical Devices ("Revised RSAMD"), which will go into effect on June 1, 2021.[1] The National Medical Products Administration ("NMPA") subsequently released several draft updates to the corresponding implementing regulations for the Revised RSAMD on March 26, 2021.[2]

The Revised RSAMD officially adopts a nationwide marketing authorization holder ("MAH") system for medical devices and makes clear that the medical device MAH is responsible for the safety and efficacy of the device throughout its whole life cycle. Aligning with the revised Drug Administration Law ("DAL") (see our previous client alert on the revised DAL here), the Revised RSAMD also adopts similar priority programs to encourage innovation, such as priority review and conditional approval for innovative medical devices. It also addresses a number of other issues, such as clinical evaluation requirements, medical device traceability, and enhanced enforcement. This client alert highlights and summarizes important takeaways of the Revised RSAMD.

Expansion of MAH System Nationwide

The Revised RSAMD officially adopts the MAH system for medical devices nationwide, which began as a pilot program on a limited scale in 2017[3] and was later expanded to 21 provinces and municipalities in 2019. The MAH system allows domestic research institutions and

[1] See PRC State Council Order No. 739, Regulation for Supervision and Administration of Medical Devices (2021), available at http://www.gov.cn/zhengce/content/2021-03/18/content_5593739.htm. The original RSAMD was issued in 2000, and was later restructured with a full revision in 2014 and a minor revision in early 2017.

[2] See Draft for Review released by the Ministry of Justice, available at http://www.moj.gov.cn/government_public/node_657.html.

[3] See Shanghai Food and Drug Administration's Notice on Implementing the Medical Device Pilot Program in Shanghai Free-trade Zone, available at http://yjj.sh.gov.cn/zl-sjfb/20191212/0003-39998.html; see also NMPA's Notice on Expanding the Medical Device MAH Pilot Program, available at http://www.gov.cn/zhengce/zhengceku/2019-11/15/content_5452302.htm.

enterprises to hold marketing authorizations for medical products with contract manufacturing arrangements, rather than having to establish their own manufacturing facilities.

The Revised RSAMD allows a foreign entity to be the MAH, but it does not indicate whether a foreign MAH must also use an ex-China manufacturing site. Under current practice, if the manufacturing location is in China, the license holder must be in China, and if the manufacturing location is outside of China, the license holder must be outside of China.

The Revised RSAMD stipulates that a medical device MAH is ultimately responsible for the safety, quality, and efficacy of the device throughout its whole life cycle and sets forth a concrete, consolidated list of MAH responsibilities and obligations, including research and development, manufacturing, distribution, and post-marketing surveillance. A foreign MAH must designate a domestic enterprise (an agent) to fulfill these obligations.

- For manufacturing, the MAH can either have its own manufacturing facilities or contract out to one or multiple contract manufacturer(s) (although contract manufacturing is prohibited for implantable medical devices with high risks). Either way, the MAH remains ultimately responsible for the quality management of the entire manufacturing process, and should ensure that the production is carried out in accordance with legal and regulatory requirements.
- For distribution, the MAH may distribute its own devices and/or supervise distributors to ensure the effective operation of the MAH's quality management system. If they distribute their own registered or filed devices, MAHs are exempt from obtaining a medical device distribution license.

Encouragement of Innovation

The Revised RSAMD promotes and emphasizes the importance of innovation. For example, Article 8 permits priority review and approval of innovative medical devices; Article 9 calls for support for the promotion and application of new medical devices technologies; and Article 26 encourages medical institutions to undertake clinical trials of innovative medical devices. These measures align with a 2017 policy document issued by the General Offices of the State Council and the Communist Party, which is referred to as the "Innovation Opinion"[4] (see our previous client alert on the Innovation Opinion here).

Priority Review

The Revised RSAMD codifies China's existing commitment to encourage high-quality clinical medical device innovation,[5] stating that priority review and approval will be available for medical devices that seek approval for rare diseases, oncology, geriatric diseases, and pediatric diseases, and for urgently-needed medical devices that have no similar products approved in

[4] See Opinions on Deepening Reform of the Evaluation and Approval System and Encouraging Innovation of Drugs and Medical Devices, available at http://www.gov.cn/zhengce/2017-10/08/content_5230105.htm.

[5] See CFDA Notice in Issuance of the Medical Device Priority Review Procedures, available at https://www.nmpa.gov.cn/xxgk/ggtg/qtggtg/20161026164001187.html, see RSAMD Art. 8.

China.[6] NMPA issued the "Priority Review Procedure for Medical Devices" and the "Special Review Procedure for Innovative Medical Devices"[7] and in 2016 and 2018 respectively, which established the priority review pathway.[8] Corresponding priority review policies also have been issued by many provinces.[9]

Conditional Approval

The Revised RSAMD adopts the conditional approval pathway that was authorized by prior guidelines. In 2019, NMPA issued its Guidelines for Conditional Approval of Medical Devices, which established a preliminary conditional approval pathway for medical devices for life-threatening illnesses for which there is no effective treatment.[10] The Revised RSAMD provides clearer guidance and a broader scope for the conditional approval pathway: if effectiveness is demonstrated through early-stage clinical trial data, medical devices that treat rare diseases and life-threatening illnesses for which there is no effective treatment, and medical devices for which there is an urgent public health need, can be approved on the condition that studies are completed post-marketing.[11] Failure to complete the required post-marketing research and establish the required risk management measures could result in the revocation of the medical device license.

Emergency Use

The Revised RSAMD incorporates the emergency use program, which can be used in government-declared public health emergences. NMPA issued its original Emergency Approval Procedure in 2009, and deployed this procedure during the pandemic to approve a number of COVID-19 test kits.[12]

One-time Importation of Medical Devices for Urgent Clinical Need

The Revised RSAMD empowers NMPA to authorize provincial medical products administrations ("PMPAs") to approve the importation of a small amount of unapproved medical devices when there is an urgent clinical need.[13] NMPA has authorized Hainan PMPA to approve this kind of one-time importation in the Hainan Bo'ao Medical Tourism Pilot Zone since 2018, and the Revised RSAMD expands this authority nationwide.[14] The application for one-time import must

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[6] Medical Device Priority Review Procedures Art. 2.

[7] See Special Review Procedure for Innovative Medical Devices, available at https://www.nmpa.gov.cn/ylqx/ylqxggtg/ylqxqtgg/20181105160001106.html.

[8] See Priority Review Procedure for Medical Devices, available at https://www.nmpa.gov.cn/xxgk/ggtg/qtggtg/20161026164001187.html.

[9] See e.g., Class II Medical Device Priority Review Procedures in Shanghai, available at http://yjj.sh.gov.cn/zx-ylqx/20200107/50cba71296d5484ba29b9b745e8f6b86.html.

[10] See Guidelines for Conditional Approval of Medical Devices, available at https://www.nmpa.gov.cn/xxgk/ggtg/qtggtg/20191220165501815.html.

[11] Revised RSAMD, Art. 19.

[13] Revised RSAMD, Art. 57.

[14] See State Council's Notice on Suspension of the Implementation of Relevant Provisions in RSAMD in

be submitted through a licensed medical institution, and the device must be used for the purpose stated in the application.

Laboratory Developed Tests

China's device regulations do not contain a definition of what other jurisdictions might consider a "laboratory developed test," nor has NMPA exercised enforcement discretion over IVDs developed and used in the laboratory. The Revised RSAMD now seems to offer some regulatory flexibility "[f]or in vitro diagnostic reagents that do not have a product in the same category marketed in China." "Qualified medical institutions" may, according to clinical need, develop the reagents and use them within their own institutions under the guidance of medical practitioners without obtaining a medical device registration.[15]

The scope of this exemption remains unclear because the Revised RSAMD does not provide a clear definition for "qualified medical institutions" or "products in the same category." The Revised RSAMD provides that more specific implementing regulations will be formulated jointly by NMPA and NHC, which may address these questions.

Prohibition on the Import of Used Medical Devices

The Revised RSAMD prohibits the importation of "used" medical devices.[16] It does not define the word "used," however, making the scope of the prohibition ambiguous. The Revised RSAMD also is silent on whether used domestically-manufactured medical devices can be distributed in China. The Revised RSAMD continues to allow for the transfer of in-service medical devices between medical device users (i.e., medical institutions) if the transferred medical devices are safe and effective.[17]

Facilitating Medical Device Registration and Filing

The Revised RSAMD facilitates medical device registration through several reforms. For example, applicants for registration of Class I, II, or III medical devices (as opposed to only Class I, as permitted in the past) may now submit a self-inspection testing report as part of the registration documents, instead of having to engage a qualified third party to issue such a testing report.[18] The Revised RSAMD also exempts innovative medical devices that have not yet been marketed overseas from submitting the marketing authorization in foreign jurisdictions

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Hainan Boao Le Cheng Medical Pilot Zone, available at http://www.gov.cn/gongbao/content/2018/content_5283176.htm.

[15] Revised RSAMD, Art. 53.

[16] See Revised RSAMD, Art. 57; List of Used Mechanical and Electronic Products Banned from Importation issued by General Administration of Customs, Announcement No. 37 of 2001 and Announcement No. 25 of 2002 (the second and fifth batches). The draft of the RSAMD amendment released in 2018 provided that "the importation and sale of used medical devices shall be prohibited." See the RSAMD 2018 (Draft for Review), Art. 48. The word "sale" has been removed from the final version of the Revised RSAMD.

[17] See the RSAMD 2017, Art. 41, the Revised RSAMD, Art. 56.

[18] Revised RSAMD, Art. 14.

when applying for registration in China. This means that imported medical devices do not have to wait for marketing authorization abroad to register in China.[19]

Clinical Evaluation Reform

The Revised RSAMD formally adopts a series of prior reforms on clinical evaluations required to support marketing for certain medical devices.

Clinical Trial Implicit Approval

Similar to the implicit approval system for drug clinical trials, the Revised RSAMD adopts an existing system that permits clinical trials to proceed in accordance with the submitted protocol if there is no objection from the NMPA within 60 days of the date of filing the application. NMPA has been implementing this system for new medical device trials since 2019.[20]

Clinical Evaluation Exemption

There is now an exemption from the clinical evaluation requirement for certain devices. The previous version of the RSAMD required that all medical device registration or record-filing applications include clinical evaluation reports (which may or may not include clinical trial reports). Class I devices and certain other types of devices were exempt from clinical trials.[21]

Under the Revised RSAMD, medical devices that meet certain criteria are exempt from clinical evaluations entirely, regardless of the class of the device.[22] For medical devices that are not exempt from clinical evaluation reports, clinical trials are required if the existing clinical materials and data are not sufficient for verifying the safety and efficacy of the medical device.

Expanded Access Programs

The Revised RSAMD adopts an expanded access pathway for investigational medical devices. Under this pathway, a sponsor of a clinical trial in China can apply to establish an expanded access treatment program for patients with life-threatening illnesses who otherwise do not qualify for a clinical trial. The NMPA and the NHC issued implementation rules for this pathway in March 2020.[23]

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[19] Revised RSAMD, Art. 15.

[20] See NMPA Notice on Adjusting the Medical Device Clinical Trial Approval Procedures (No. 26 2019), available at https://www.nmpa.gov.cn/zhuanti/ypqxgg/ggzhcfg/20190401164701503.html.

[21] See RSAMD 2017, Art. 17.

[22] See Revised RSAMD, Art. 24.

[23] See NMPA Notice on the Medical Device Expanded Access Programs Administration Rules (No. 41 2020), available at https://www.nmpa.gov.cn/xxgk/ggtg/qtggtg/20200320153801192.html.

Medical Device Distribution

New Exemption for Medical Device Distribution Filing

The Revised RSAMD creates a new exemption allowing certain Class II devices to be distributed without a record-filing (for corresponding device distributors) if their safety and effectiveness are not affected by the distribution process.[24] Unlike the previous draft of the RSAMD released in 2018, which provided that "certain Class II devices could be distributed without the record-filing (for corresponding device distributors) if their safety and effectiveness could be *guaranteed* by routine management" and that NMPA would issue a "catalogue" of exempt devices,[25] the Revised RSAMD does not require a guarantee of safety and effectiveness. There also is no mention of a catalogue in the Revised RSAMD.

Medical Device Online Distribution

Consistent with the existing "Medical Device Online Distribution Administration Rules" issued in 2017,[26] the Revised RSAMD allows MAHs and licensed medical device distributors to sell medical devices online and provides more detailed requirements for online distribution of medical devices.[27] The MAH or distributor must distribute the device through its own website or through a third-party platform. Third-party online medical device distribution platforms must complete a record-filing process, and are required to check the qualifications of the distributor's license and manage the medical device distribution that occurs on the platform.[28]

Penalty Exemption for Certain Distributors

The Revised RSAMD establishes a new administrative penalty exemption for distributors that have diligently fulfilled their incoming goods inspection obligation.[29]

Improvement of the Medical Device Traceability System

The Revised RSAMD adopts traceability obligations for the MAH, including the unique identifier system for medical devices.[30] Specifically, applicants and filers are required to ensure their filing materials are "traceable,"[31] MAHs are required to establish a product tracing system, and medical device distributors and users, such as hospitals, are required to retain appropriate

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[24] Revised RSAMD Art. 41.

[25] See RSAMD 2018 (Draft for Review), Art. 33.

[26] See Medical Device Online Distribution Administration Rules, available at https://www.nmpa.gov.cn/ylqx/ylqxfgwj/ylqxbmgzh/20171222201001323.html.

[27] Revised RSAMD, Art. 46.

[28] Revised RSAMD, Art. 46.

[29] Revised RSAMD, Art. 87.

[30] See Revised RSAMD Art. 14, Art. 20, and Art. 38.

[31] Revised RSAMD Art. 14.

records and implement the medical device traceability system.[32] The Revised RSAMD codifies the reforms contained in the "Rules for Medical Device Unique Identification System," under which MAHs and medical device manufacturers are required to assign a unique identifier code—generated in accordance with uniform coding rules—to each product packaging unit.

Enhanced Penalties

Consistent with the trend in food, drug, and medical device regulations in China over the last several years, the Revised RSAMD contains increased monetary (i.e., increased fines) and other penalties for violations by entities and responsible individuals.

Increased Liability at the Individual-Level

The Revised RSAMD explicitly provides that legal representatives and directly responsible personnel may be individually liable for prohibited acts, including monetary fines and debarment sanctions. While these types of individual penalties are not new, the maximum penalty is now lifetime debarment from the medical device industry in certain cases.[33]

Liability for Violation of Medical Device GCPs

The Revised RSAMD expands the liability for violation of rules related to medical device clinical trials. For example, the Revised RSAMD explicitly provides that a clinical institution (i.e., a medical institution) that violates good clinical practices (GCPs) for medical devices may be subject to an order to rectify or cease the trial and monetary penalties. Moreover, the legal representative, responsible persons, and personnel in charge may also have income from the period of violation confiscated, and a fine of 30% to 3 times the income.[34]

If you have any questions concerning the material discussed in this client alert, please contact the following China-focused members of our Food, Drugs, and Devices practice:

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[32] Revised RSAMD Art. 45.

[33] Revised RSAMD Art. 83.

[34] Revised RSAMD Art. 94.