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China Issues Raft Of Regulatory Notices: Guidelines, Standards And More Reforms

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By Ashley Yeo

THE JANUARY 2019 ASIAN MEDTECH ASSOCIATIONS Regulatory Networking discussions focus on the volume of activity within China's agencies in issuing guidances, technical standards, and in review updates. This series is hosted by Medtech Insight, along with the Asia Regulatory and Quality Consultancy (ARQon) and the Asia Regulatory Professionals Association (ARPA).

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The past two months have seen the Chinese government issue many updates for the medical technology industry, in both summaries of technical guidance and China unique standards; and in changes to the medical device review process.

These high-level updates include the National Medical Products Administration's (NMPA, formerly the CFDA) release of four registration technical review guidelines; and 27 new industry standards for medical devices, listed in this NMPA link (all links in Chinese). Three of the guidelines are here, and the fourth is here. The NMPA has also released a notification on the 2019 revision program of medical device industry standards, including updates and new drafts.

Innovative Device Catalog Listing Provides Commercial Advantages

Under planned reforms of the review process, the Ministry of Science and Technology (MOST) has released a notification about its 2018 Innovative Medical Device Catalogue. If a company's product is listed in the catalog, it might get a faster reimbursement or a better price. It also means it should be easier to win tenders in future. "The majority of companies included are local China companies," says Wen

Peng, who is director of regulatory affairs, Asia-Pacific, at Edwards (Shanghai) Medical Products Co Ltd, based in Beijing, part of Edwards Lifesciences Corp.

She explained that products are included in the catalog via an innovative fast-track process, and are then certificated for future commercial purposes. This is separate to the existing reimbursement listing process. If a company is entered in the catalog, the Chinese provinces will give the company "extra points" when it applies for reimbursement. In this way, the reimbursement process is made easier. But crucially, being in this newly-published innovation catalog helps companies when they submit for tenders.

These products must have a local patent, or they don't get into the innovative process, Peng notes.

Elsewhere, the NMPA has released a notice on a guideline on Submission Materials for Innovative Medical Devices Special Review. This makes changes to existing procedures, for example, after the company secures an innovative patent, it now needs to apply for medical device registration within five years. After that, the NMPA will no longer accept the "innovative medical device application." This means that when companies start to apply for patents in China, they need to be mindful of when they will start working on the innovative medical device registration.

China's CDME On Registration Process Improvements

The Center for Medical Device Evaluation (CMDE), the body responsible for conducting dossier review during the registration process, has started a discussion to develop a Group Decision Mechanism for Medical Device Registration Reviews. It is considered by the CDME that when it comes to device innovations, a reviewer should not make the final decision by her or himself; it should be a group discussion on how to approve the product.

Accordingly, the CDME and the NMPA have issued new guidance on how to set up such groups. Speaking for industry, Peng said, "We see this as an improvement on the previous system." This is because, traditionally, a single reviewer could have decided, wrongly, to reject an application, and that decision would have stood. "Group situations are fairer." But industry is also concerned about reviews being delayed because of the new process. However, the process is already underway for some high-risk products, where a review leader is responsible for the majority of the review, and other staff are assigned to do two further checks.

Another option is simply to split the overall job among, say, clinical or biocompatibility experts, and the risk of wrong decisions is reduced in that way too. These are the two options already being used. But for the future, there is a drive to emulate the methods of the Australian TGA, which always uses several reviewers to look at component parts of an application. The new CDME process was released on the website on January 4, following drafting in 2017 and 2018.

The CDME is also soliciting comments on the Master Document Registration System of Medical Devices. For many medical devices and some consumer devices, the materials information requested by the CDME is very detailed – and most finished-product companies do not produce those particular materials themselves. They are usually sourced from external suppliers, and as the information about them is usually highly confidential, the supplier will not normally agree to disclose it to the applicants.

But in some situations, the suppliers are prepared to disclose details to the NMPA or CMDE, because there would be fewer concerns about copying and disclosure. So now, the authorities are setting up a mechanism to allow suppliers to disclose information about specific chemicals or materials for the master file, which would be sent to the reviewing center. The information would be given a master code held by the supplier, and when companies file a product that uses the material, they would simply need to cite the vendor and the code.

Thus, if the NMPA approved a file from one company that included the material, subsequent companies' documents would not need to be reviewed. This spares disclosure of confidential information, and reduces the risks for materials vendors. That, at least, is the intention of how the procedure should work at the reviewing center. A similar process started to be developed some years ago, but there was no formal process.

Supervision Of Devices Regulation Update Awaited in China

Industry in China still awaits an update to State Council Decree No. 650 Order (Regulations for the Supervision and Administration of Medical Devices), which became effective in 2014. On May 19, 2017, Order 680 updated that legislation, and in June 2018, it was updated for a second time, with the new draft sent out for public comment. The most recent update is still under review at the State Council. Industry expects the new regulation to be released in the first half of 2019, but information is scant.

On the subject of the use in China of overseas clinical data, where accepted, these must be clinical study data, not real-world evidence (RWE). It is also understood that the product in question has to prove that the data do not show up racial differences, i.e. that the overseas data can be applied for the local population in China. It can be difficult for companies to prove the "no-racial-difference" factor. The best way is to initiate a clinical trial in China locally, and compare it with the overseas data. Some products are exempted from China local clinical trials, but that status is very difficult to achieve.

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