CFDA ANNOUNCES NEW MEDICAL DEVICE CLASSIFICATION CATALOGUE

On 31 August 2017, the China Food and Drug Administration (CFDA) announced a new Medical Device Classification Catalogue. The new Catalogue will be implemented on 1 August 2018 and replace the current Catalogue of 2002. Reasons for this amendment include that the current Catalogue is not detailed enough affecting a unified registration and approval procedure, and difficulties in covering new products and categories due to the lack of updates over time. The major changes that should be kept in mind by (medical) device companies operating in China are as follows.

Firstly, the risk qualification of 40 medical devices is downgraded to either Class I or Class II. In addition, the risk qualification of certain types of medical devices is upgraded to Class III. Medical devices are classified based on their risks; Class I are considered to be low-risk, Class II are those with moderate risks, and Class III are associated with relatively high risks. Such classification determines the procedure that the medical device has to go through before entering the Chinese market. Class I medical devices have to go through a record-filing procedure, whereas Class II and Class III medical devices should be examined and approved first. Therefore, the new Catalogue and its revised medical device classification directory shall have a significant impact on the admission procedure of medical devices.

Furthermore, the number of medical device categories, which is based on its functions and medical uses, is reduced from 43 to 22. For each medical device category, the new Catalogue contains a division between primary and sub-categories, product description, intended medical use, product name examples, and classification (I, II and III). Hereby, the current 260 device categories are reclassified into 206 primary categories and further subdivided into 1,157 sub-categories. Moreover, a more detailed description of the medical device features and intended medical uses is added to each category, which is intended to provide more clarity for medical device applicants for classifying a specific medical device. Lastly, the new Catalogue includes 6,609 examples of medical devices, as opposed to 1,008 that were listed in the current Catalogue.

All in all, the new Catalogue is more comprehensive compared to the current Catalogue in order to provide applicants with more clarity and address changes in technology. However, it is important for medical device companies to check whether their products will still fall under the same Class when the new Catalogue enters into force and adjust their plans accordingly.

Regulatory developments regarding medical devices in China are carefully monitored by our team. Please feel free to contact us for questions or more information: snb@snblaw.com.