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Ministry of Justice
No. 6 Chaoyangmen South Street
Chaoyang District
Beijing
People's Republic of China

RE: Proposed Changes to the China Regulations for the Supervision and Administration of Medical Devices

Your Excellency:

As the leading trade association representing the manufacturers of medical imaging devices and radiopharmaceuticals, the Medical Imaging and Technology Alliance (MITA) is taking the opportunity to present comments on existing text and proposed amendments to China Regulations for the Supervision and Administration of Medical Devices in Decree 680. MITA urges the China National Drug Administration (CNDA) to make the following changes to the proposals:

Article No.	**680 Section**	**MITA Suggested Changes**	**Comments**
Article 6	Medical devices shall meet the mandatory national standard or mandatory industry standard when there are no relevant mandatory national standard available.	Medical devices shall meet the mandatory national standard or mandatory industry standard when there are no relevant mandatory national standard available**, a product technical requirement approved by the drug regulatory department under the State Council, or an international standard where an equivalent or higher level of performance or safety can be demonstrated.**	Some mandatory standards are formulated or updated so as to be relatively lagging, which may be inconsistent with international standards, which may hinder the development of the medical device industry and cause certain difficulties for enterprises.
Article 9	"Where clinical evaluation is required for the application for the registration of Class II and III medical devices, clinical evaluation materials of	"Where clinical evaluation is required for the application for the registration of Class ~~**II and**~~ III medical devices, clinical evaluation materials of medical devices should also be	The risk of Class II MD is low and the technology is more mature. Therefore, documents for clinical evaluation are not needed to demonstrate safety and effectiveness.

	medical devices should also be submitted as required."	submitted as required."	
Article 11	For the innovative medical device that is not marketed at home and abroad, it is allowed that the supporting documents for marketing authorization of the medical device granted by the competent authority of the country (region) where the registration applicant is located are not submitted."	For the ~~**innovative**~~ medical device that is not marketed at home and abroad, it is allowed that the supporting documents for marketing authorization of the medical device granted by the competent authority of the country (region) where the registration applicant is located are not submitted."	The requirement for country of origin approval for imported products, delays market introduction of state of the art technologies to patients in China. As such, imported products should not be required to get country of origin approval before submission to CNDA.
Article 15	"Medical Device Registration Certificate or Filing Certificate of the overseas medical device marketing authorization holder should indicate the name, address, contact information and other information of the agent."	"Medical Device Registration Certificate or Filing Certificate of the overseas medical device marketing authorization holder should indicate the name, address, ~~**contact information and other information of the agent.**~~"	Article 16 stipulates that in case that if non-substantial change occurs and will not affect the safety and effectiveness of the medical devices, the registration applicant shall file the change on record with the original registration authority. It is more common for the agent to change the contact information. Such information in the registration certificate will increase the unnecessary burden on the review and approval department and the applicant. It is recommended that the agent and contact information be reflected only in the label and the manual.
Article 19	"The filing of Class I medical devices requires no clinical evaluation; the registration of Class II medical devices requires no clinical evaluation in principle; the registration of Class III medical devices requires clinical evaluation.	"The filing of Class I medical devices requires no clinical evaluation; the registration of Class II medical devices requires no clinical evaluation ~~**in principle**~~; the registration of Class III medical devices requires clinical evaluation.	The risk of Class II MD is low and the technology is more mature, do not need documents for clinical evaluation to demonstrate safety and effectiveness
Article 19	"Class III medical devices that are used for supporting or sustaining life or have high risks in clinical use, clinical trials should be conducted in principle."	"Class III medical devices that are used for supporting or sustaining life, **and are not based on well understood or well established technology**, or have high risks in clinical use **which in the list that need to conduct clinical evaluation** , clinical ~~**trials**~~ **evaluation** should be conducted ~~**in principle**~~."	A clear list of clinical evaluations should be given according to the level of risk. Some life supporting / life sustaining technologies have been in use for years with established technology, such as anesthesia and respiratory devices. Clinical trials for these devices should not be necessary, as clinical safety has already been demonstrated through real world use over the years.

Article 28	"Holders of medical device marketing licenses shall carry out self-inspections on the quality management system operation on a regular basis and submit self-inspection reports to the drug regulatory departments of the people's governments of the provinces, autonomous regions and municipalities directly under the central government. Where, the holders of overseas medical device marketing licenses shall submit a self-inspection report to the drug regulatory department under the State Council through its agent. The agent of the holder of the overseas medical device marketing license shall report the relevant agency information to the drug regulatory department of the people's government of the province, autonomous region, or municipality directly under the central government."	"Holders of medical device marketing licenses shall carry out self-inspections on the quality management system operation on a regular basis ~~and submit self-inspection result to the drug regulatory departments of the people's governments of the provinces, autonomous regions and municipalities directly under the central government. Where, the holders of overseas medical device marketing licenses shall submit a self-inspection report to the drug regulatory department under the State Council through its agent.~~ The agent of the holder of the overseas medical device marketing license shall report the relevant agency information to the drug regulatory department of the people's government of the province, autonomous region, or municipality directly under the central government."	The revised text reflects the fact that self-audit reports are not required to be submitted in detail for any other global regulatory system. Additionally, a more detailed evaluation of the manufacturer self-checks could be conducted during on-site inspections.
Article 29	If the production conditions of medical devices change and no longer meet the requirements of the quality management system for medical devices, holders of medical device marketing licenses shall take immediate rectification action. If safety and effectiveness of medical devices may be affected, holders of medical device marketing licenses shall immediately stop production activities and report to the drug regulatory departments of the people's governments in the provinces, autonomous regions, and municipalities directly under the central government; where, holders of overseas medical device marketing	If the production conditions of medical devices change and no longer meet the requirements of the quality management system for medical devices, holders of medical device marketing licenses shall take immediate rectification action. ~~The manufacturer shall take appropriate actions, commensurate with risk management and corrective and preventive action to ensure the safety and effectiveness of products. If the manufacturer finds that the medical devices being produced pose a risk to public health or safety or contain unmitigated risks of a serious nature, it shall immediately stop production and~~ report to the drug	Actions taken to address a non conforming product should be risk based, under the Quality Management System. This is consistent with international regulatory approach such as US FDA, ISO 13485, etc.

	licenses shall report to the drug regulatory department under the State Council through agents.	regulatory departments of the people's governments in the provinces, autonomous regions, and municipalities directly under the central government; where, holders of overseas medical device marketing licenses shall report to the drug regulatory department under the State Council through agents.	
Article 48	"The import and sales of medical devices that have been used should be prohibited."	"The import ~~**and sales**~~ of medical devices that have been used **and whose quality cannot be guaranteed by original MAH** should be prohibited. **Exceptions as follows** **1. Medical equipment returned to the factory for repair.** **2. Medical devices for display"**	In keeping with the existing AQSIQ regulation, this clause should be consistent and limit the import of used medical devices but not the sale of used medical devices within China. Additionally, medical device exporters should be able to import devices for repair activities or non-medical uses such as display.
Article 48	/	Propose to add following sentence to article 48 **"After a high-value medical device has completed the clinical trial in the clinical trial institution. If the registration certificate has been obtained and approved by the competent department, the holder of the medical device marketing license guarantees that the production quality system meets the relevant requirements. It can be sold to the clinical trial institution which conducted the clinical trial**	Some medical devices are very expensive, and medical device clinical testing institutions also need to invest heavily in the installation of this device. Deinstallation of these devices causes clinical disruption and adds additional cost to the healthcare system, as well. If such a medical device is deinstalled and removed after the clinical trial is completed, it will impose significant burden to society, clinical trial institutions and manufacturers.
Article 57	If holder of medical device marketing license medical device manufacturers find that the medical devices manufactured do not meet mandatory standards, product technical requirements registered or filed or have other deficiencies, they shall	If holder of medical device marketing license medical device manufacturers finds that the medical devices manufactured do not meet mandatory standards, product technical requirements registered or filed or have other deficiencies **that will bring unacceptable safety**	Actions taken to address a non-conforming product should be risk based, under the Quality Management System. This is consistent with International Regulator approach such as US FDA, ISO 13485, etc.

	immediately stop manufacturing, notify relevant manufacturers, distributors and consumption units, and consumers to stop distributing and using the medical device, recall marketed medical device and take remedy...	**risks, as evaluated by the manufacturer's QMS**, they shall immediately stop manufacturing, notify relevant manufacturers, distributors and consumption units, and consumers to stop distributing and using the medical device, recall marketed medical device and take remedy...	
Article 62	"It is forbidden to produce, operate or use counterfeit medical devices. "Any one of the following cases may be considered as a counterfeit medical device: (1) Producing or importing medical devices without obtaining the registration certificate or record-keeping certificate as required for dealing with medical devices; (2) Using non-medical devices as medical devices, or deliberately using a different medical device to take the stead of the required type of medical device; (3) Taking fraudulent means to obtain the medical device registration certificate or the record-keeping certificate to produce or import medical devices; (4) Forging or falsely using another person's registration certificate or record-keeping certificate for medical devices, enterprise name or production address, etc.	"It is forbidden to produce, operate or use counterfeit medical devices. "Any one of the following cases may be considered as a counterfeit medical device: (1) **Release from production** or importing medical devices without obtaining the registration certificate or record-keeping certificate as required for dealing with medical devices (**exceptions include medical devices for clinical trials or registration tests**) (2) Using non-medical devices as medical devices, or deliberately using a different medical device to take the stead of the required type of medical device; (3) Taking fraudulent means to obtain the medical device registration certificate or the record-keeping certificate to produce or import medical devices; (4) Forging or falsely using another person's registration certificate or record-keeping certificate for medical devices, enterprise name or production address, etc. **(5) A medical device that is identified as smuggled by a non-legal authorized distributors.**	The date of release from production date should be on or after the license date. The safety and quality of smuggled devices cannot be guaranteed by the manufacturer and therefore should be treated as a counterfeit medical device.

Article 65	As to the medical devices that may contain harmful substances or whose design, raw materials and production processes have been changed or reformed without authorization as may have potential safety risks, in the case that the inspection items and inspection methods specified in the national and industrial standards can't be applied to such medical devices, the medical device inspection institution may then apply the supplementary inspection items and inspection methods approved by the drug supervision and administration authority under the State Council for inspection; the inspection results obtained from the supplementary inspection items and inspection methods may serve as the basis for the authority responsible for drug supervision and administration to determine the quality of the concerned medical device.	As to the medical devices that may contain harmful substances or whose design, raw materials and production processes have been changed or reformed without authorization as may have potential safety risks, in the case that the inspection items and inspection methods specified in the national and industrial standards can't be applied to such medical devices, the medical device inspection institution may then apply the supplementary inspection items and inspection methods approved by the drug supervision and administration authority under the State Council for inspection**; an internationally accepted method can be used if there is no inspection items and inspection methods approved by the drug supervision and administration authority under the State Council for inspection.** The inspection results obtained from the supplementary inspection items and inspection methods may serve as the basis for the authority responsible for drug supervision and administration to determine the quality of the concerned medical device.	In the absence of a national test or standard, international standards should be considered as an alternative method for showing compliance to performance and safety criteria.
Article 70 Article 72 to 76	The drug regulatory authority of the government at county level and above shall confiscate the medical devices illegally manufactured…	The drug regulatory department of people's government at **or above the provincial level** shall confiscate the medical devices illegally manufactured...	Article 59 stipulates the medical device production activities shall be supervised and inspected by the drug regulatory department of people's government at or above the provincial level, it should be consistent with this article.

Article 73	"The import and sales of medical devices that have been used should be prohibited."	"The import ~~**and sales**~~ of medical devices that have been used should be prohibited. **Exceptions as follows** **1. Medical equipment returned to the factory for repair.** **2. Medical devices for display"**	In keeping with the existing AQSIQ regulation, this clause should be consistent and limit the import of used medical devices but not the sale of used medical devices within China. Additionally, medical device exporters should be able to import devices for repair activities or non-medical uses such as display. Note that this is identical to Article 48
Article 73		Propose to add following sentence to article 48 **"After a high-value medical device has completed the clinical trial in the clinical trial institution. If the registration certificate has been obtained and approved by the competent department, the holder of the medical device marketing license guarantees that the production quality system meets the relevant requirements. It can be sold to the clinical trial institution which conducted the clinical trial."**	Some medical devices are very expensive, and medical device clinical testing institutions also need to invest heavily in the installation of this device. As well, deinstallation of these devices causes clinical disruption and adds additional cost to the healthcare system. If such MD is deinstalled and removed after the clinical trial is completed, it will impose significant burden to society, clinical trial institutions and manufacturers. Note that this is identical to Article 48
Article 87	Fees may be charged for registration of medical devices, and fees may be charged on an annual basis for supervision of production sites and product varieties of medical devices. The specific charging items and charging standards shall be respectively determined by the relevant finance and price-setting authorities under the State Council in accordance with the relevant provisions of the state.	Fees may be charged for registration of medical devices, ~~**and fees may be charged on an annual basis for supervision of production sites and product varieties of medical devices. The specific charging items and charging standards shall be respectively determined by the relevant finance and price-setting authorities under the State Council in accordance with the relevant provisions of the state.**~~	This would increase business burden, and should be deleted.

If you have any questions, please don't hesitate to contact Carolyn Hull, Manager, Global Regulatory Standards (chull@medicalimaging.org/703-841-3242).

Thank you for your consideration.

Sincerely,

Patrick Hope
Executive Director, MITA

MITA is the collective voice of medical imaging equipment and radiopharmaceutical manufacturers, innovators and product developers. It represents companies whose sales comprise more than 90 percent of the global market for medical imaging technology. These technologies include: magnetic resonance imaging (MRI), medical X-Ray equipment, computed tomography (CT) scanners, ultrasound, nuclear imaging, radiopharmaceuticals, and imaging information systems. Advancements in medical imaging are transforming health care through earlier disease detection, less invasive procedures and more effective treatments. The industry is extremely important to American healthcare and noted for its continual drive for innovation, fast-as-possible product introduction cycles, complex technologies, and multifaceted supply chains. Individually and collectively, these attributes result in unique concerns as the industry strives toward the goal of providing patients with the safest, most advanced medical imaging currently available.