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CLINICAL EXAMINATION OF MEDICAL DEVICES AND THEIR APPROVAL PROCESS IN CHINA

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ABSTRACT:

To deploy innovative medical devices for the treatment and diagnosis of a variety of ailments, the safety of the global population is the top priority. Industry innovation and regulations collaborate to create devices for a variety of global markets while also improving the quality and safety of existing devices on the market. The most important factor for devices is to categorize the real regulatory pathway that guarantees that safety protocols and other regulatory criteria are met in a given jurisdiction. We conduct clinical studies for medical devices that are significantly different from those conducted for drug testing. The new NMPA regulation requires manufacturers of high-risk devices to submit a comprehensive overview of their data. The clinical trials regulation makes clinical trial data more transparent. In China, medical devices are regulated by China food drug, and administration. The Chinese medical device business, like the Chinese economy, is growing rapidly. For the best chance of making educated judgments about new medical devices, complete transparency is necessary.

KEYWORDS: Medical device, Clinical examination of medical device, medical device regulation, regulatory frameworks

INTRODUCTION

China is a massive nation with a plethora of medical device potential. Although China's economic growth is decreasing, the medical device business is still growing. In 2016, the Chinese medical device sector was worth US\$18.8 billion, and it is expected to increase gradually until 2019 when it would be worth more than US\$24 billion (EMERGO 2017b). China is a member of the BRIC group of countries, which includes Brazil, Russia, India, and China. The BRICs account for one-quarter of the world's area and 40% of its people. These more commodity economies have a combined GDP of \$30 trillion (or 20% of world GDP), which is expected to grow to \$120 trillion by 2050. (Watch 2015).

At present moment, China's medical products market is rated second in the world. The market has been rising at around 20% per year since 2009, driven by both an increase in discretionary money and a population that is aging quicker than any other country's population. By 2020, China will have 400 million population aged 60 and over, including 100 million aged 80 and up. Because of the scale of the Chinese industry and the expected rise in demands for medical products, China has become a vital industry for medical device companies to enter. The earlier a firm can get its medical device products approved in China, the faster it can reap the benefits of the income generated by the Chinese market. Organizations interested in joining the Chinese market, on the other hand, are aware that they must overcome existing hurdles in a regulatory environment that is unclear and evolving.

In China, rising prosperity is accompanied by an increase in the incidence of cancer, heart disease, diabetes, and other chronic illnesses among the population. As per a WHO estimate, China had almost three million newly diagnosed cancer cases in 2012, accounting for over 22% of the worldwide total, and 2.2 million cancer deaths, accounting for 27% of the global total. While the regulatory pathways in the other major areas, such as the EU and the US, are very well, China is a region with more unpredictability and less predictable.

Many more of China's 27,000+ hospitals will have to be updated or rebuilt in the coming years to fight the country's mounting health problems. Furthermore, the Chinese government expects foreign-owned hospitals, which were formerly heavily controlled or prohibited, to fill part of the space. In August 2015, China launched a trial initiative in which foreign investors might create completely foreign-funded hospitals in seven of its cities and provinces, either through purchase or greenfield development (MAINE 2015). This is only one of China's numerous ongoing programs. The National Planning Guideline for the Healthcare Service System (2015–2020), China's first detailed five-year healthcare blueprint, sets clear targets for 2020, including one clinic and one medical service center for each society with a community of over 30,000 people and 1.2 hospital beds for every 1,000 people in the community (FULBRIGHT 2016).

This growing investment in hospitals, health centers, and medical centers gives medical device businesses a huge chance to get large contracts for their healthcare medical devices. The market forces that encourage hospitals to seek out and buy innovative technology are helping medical device companies (Daemmrigh 2013). Obtaining regulatory clearance to reach the Chinese market for your company's medical device, as well as ensuring compliance to maintain the medical device on the market, is a vital component of this. The regulatory affairs professionals are tasked with developing and implementing a regulatory strategy that gives the company the quickest time to marketplace and the most certainty. This is very difficult for the regulatory person in the current context. The increasing complexity and widespread use of medical devices have signalled the need for more severe and well-defined regulations. In our modern civilization, the United States and China serve as two prominent examples of medical device regulation. More significantly, they show the evolution and considerations needed for regulatory regulations at various phases of medical device developments in different global settings. While the transnational character of modern technology has resulted in growing synergy between nations and their regulatory frameworks, basic cultural differences and growth impulse have allowed the two to expand both together and apart. The background and evolution of medical device regulation in the United States and China are examined in this article. A comprehensive examination of each country's journey to its current level of medical device regulation will highlight the political and sociological obstacles each faced, as well as how these obstacles caused regulation in the two nations to grow in two distinct ways.

Medical device Chinese companies should educate themselves with the new laws and evaluate how they will affect their company and strategy. The regulatory professional's job is to comprehend new rules and communicate them to the rest of the company so that projects may be planned effectively. Because the restrictions are new, regulatory professionals are faced with issues in handling the push from the businesses to get access to and keep their company's medical products on the Chinese market. The relevance of the Chinese market to the firm, along with the challenges posed by new Chinese legislation, makes this article a timely and relevant issue for the medical device industry^[1,2].

Definition (As per Chinese regulatory agencies)

A medical device is Any apparatus, instrument, material, appliance, or other article whether used alone or in combination, including the software necessary for its proper application. It has a primary effect in or on the human body that is not achieved by pharmacology, immunology, or metabolism, but which may be aided in its function by such means; its usage is to fulfil the following stated objectives:

1. Diagnosis, monitoring, prevention, treatment, or alleviation of disease;
2. Diagnosis, treatment, monitoring, alleviation of, or compensation for an injury or handicap conditions;
3. Investigation, replacement, or modification for anatomy or a physiological process;
4. Control of conception ("Regulation," 2012)².

Medical device Classification

Medical devices are classified and administered according to their risk categories under the New Regulations. Class I medical devices have a low overall risk and can be safely and effectively administered regularly; Class II medical devices have a middle-risk level and require strict control and administration to ensure their safety and effectiveness, and Class III medical devices have a higher risk level and require special steps and strict assure their safety and efficacy. In contrast to previous laws, the new system incorporates risk assessment within the rules. Risk assessment is used not just in the device categorization sections, but also throughout the rest of the document. "Medical device registration should provide a product risk evaluation report; medical device recalls and adverse occurrences," for example³.

The State Food and Drug Administration (SFDA), which was recent times elevated to a ministerial-level agency instantly under the State Council and renamed the China Food and Drug Administration (CFDA) to reduce fracturing and consolidate power, is accountable for implementing basic device oversight regulations and overseeing their implementation. Food regulation was largely affected by the changes, although their promotion by the government has given pharmaceuticals and medical device regulators more regulatory authority and the opportunity to seek extra funding.

When unfavourable incidents are recorded, provincial and municipal authorities operate as first responders and assist the CFDA in observing and taking any action at the regional scale. The Canadian Food and Drug Administration (CFDA) is in charge of collecting, compiling, and evaluating adverse event information from all provinces and cities. Medical device manufacturers, distributors, and users must report death and due to injuries adverse occurrences to regional monitoring institutes. Healthcare canters appear to be reporting the majority of instances. The CFDA has an online database that records adverse medical occurrences, but it is not open to the public.

Product approvals are renewed every four years, based on the information gained since the first registration. Regulations have recently been created to make the re-registration process easier by requiring just new paperwork to prove the efficacy and safety of major modifications made to relevant items. Re-registration must also include device vigilance reports that summarise and analyze adverse occurrences connected to these items. Certain medication groups are obliged to do post-approval studies, but the CFDA has yet to establish equivalent rules for medical devices. Producers of newer imported medical devices, on the other hand, are said to be accumulating evidence from routine clinical work, such as with current generations of drug-eluting stents ⁴.

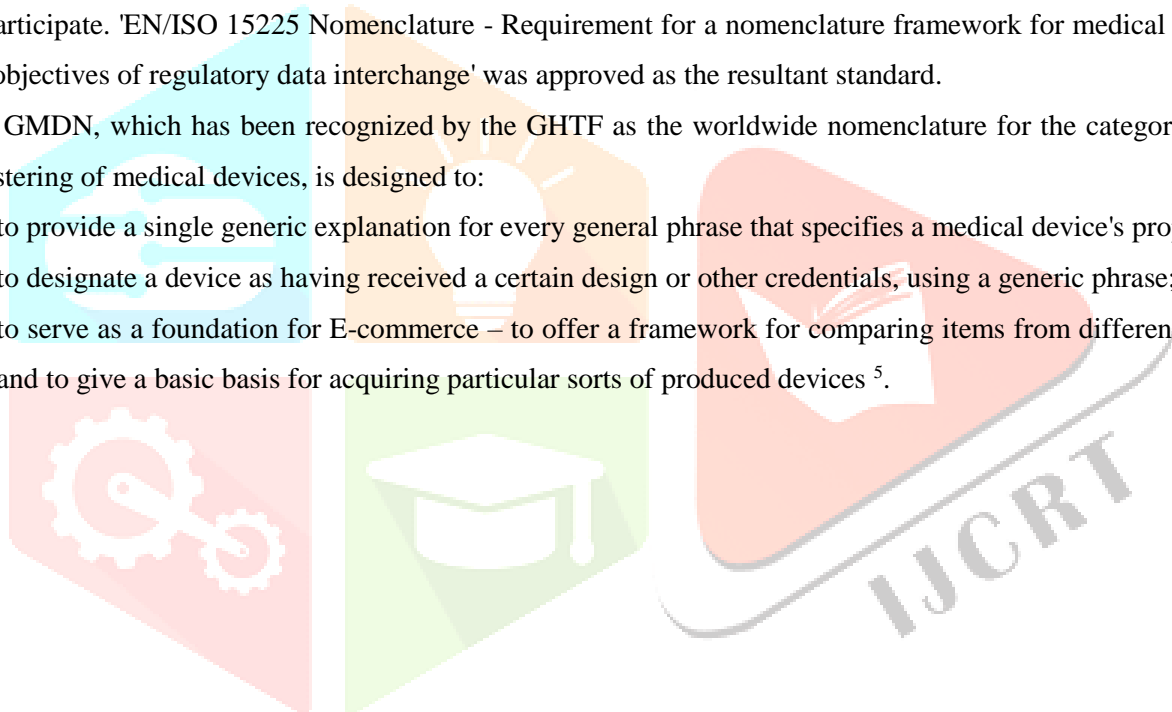
Global medical device nomenclature (GMDN)

Consistency in nomenclature is critical to achieving the overall aim of worldwide harmonization, especially when it comes to identifying devices implicated in adverse event reports.

The European Commission tasked the 'Comité Européen de Normalization' (CEN) in 1993 with developing a standard that would outline the framework of a nomenclature system that would fulfil the demands of the worldwide market. To guarantee that international matters were addressed, the International Standards Organization was asked to participate. 'EN/ISO 15225 Nomenclature - Requirement for a nomenclature framework for medical devices for the objectives of regulatory data interchange' was approved as the resultant standard.

The GMDN, which has been recognized by the GHTF as the worldwide nomenclature for the categorization and registering of medical devices, is designed to:

1. to provide a single generic explanation for every general phrase that specifies a medical device's properties.
2. to designate a device as having received a certain design or other credentials, using a generic phrase;
3. to serve as a foundation for E-commerce – to offer a framework for comparing items from different producers and to give a basic basis for acquiring particular sorts of produced devices ⁵.



Regulation and registration of medical devices in China

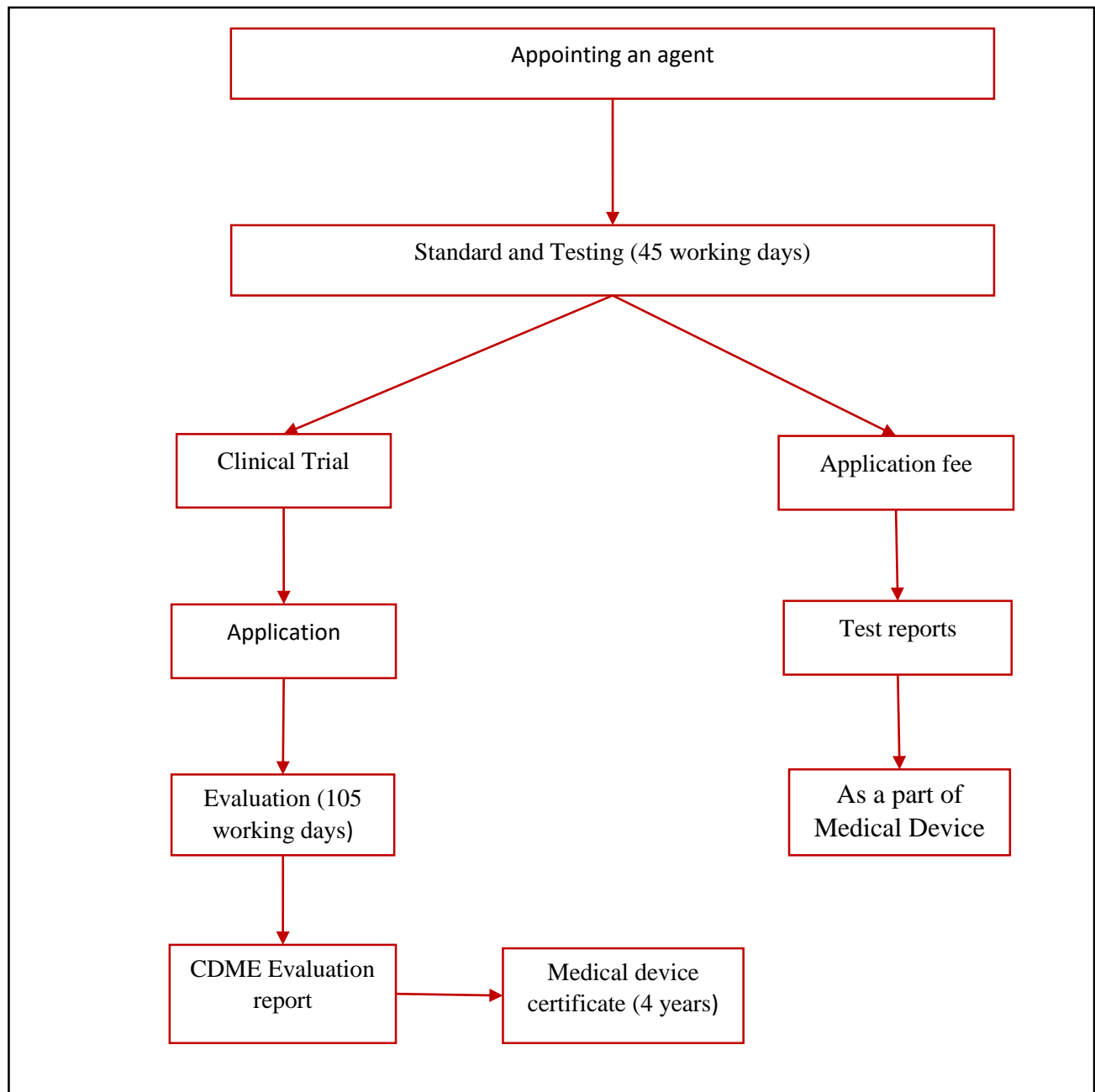


Figure 1: Registration of Medical Device process in China

Medical Device registrations may only be done by a Cense legal body, as per the Medical Device registration regulations. Medical Devices will be controlled by Chinese national standards (GB Standards) and professional/sector-based standards (YY Standards) set by the SFDA. Manufacturers must provide a statement certifying that the applicable Chinese Standards have been accepted without modifications, and if there have been any changes, the producer may add matching requirements to the SFDA on standards relevant to the device. The manufacturer must pay the necessary charge when the test is completed to ensure that the requirements are met. Figure 4 depicts the Chinese registration process in detail.

Clinical trials for Class II and III medical devices should be undertaken in China. In China, there is no requirement for obtaining clearance before carrying out tests, but the maker must inform the local regulatory body of the study's progress. The party may file to the SFDA after receiving a valid test result and a clinical trial report. The application must be written entirely in Chinese. If the application is approved by SFDA, it is submitted to CDME, where the

evaluation process begins. CDME will provide an assessment report to SFDA after the project is completed. The SFDA will grant a medical device registration certificate that will be effective for four years ⁶.

Clinical Trial and Clinical Trial Approval

A clinical study is often not necessary for the filing of Class I medical devices. Clinical trials are required for the registration of Class II and Class III medical devices in general. However, in some cases, such as if the device undergoing consideration is demonstrated to be "equivalent" to a device on the List of Medical Devices Exempted from Clinical Trials, such a criterion may be waived. Furthermore, where a device under application is "substantially equivalent" to a medical device that has been approved for registration by the NMPA, the applicant may use data from the "substantially equivalent" medical device's clinical application observation or clinical trial rather than data from the device under application's clinical trials. Information from overseas clinical trials may be acknowledged by the NMPA, subject to certain conditions, such as the foreign trial adhering to specific ethics rules and good clinical practices, and the data being authentic, scientific, and reliable.

Potential medical device importers to the PRC may be interested to know that data from foreign clinical trials may be accepted by the NMPA, subject to certain conditions, such as the oversea trial adhering to particular ethics rules and good clinical practices, and the data being authentic, research-based, and reliable.

Additionally, clinical trials involving specified high-risk gadgets are prohibited. If a device is on the list of Class III Devices Subject to Clinical Study Approvals, for example, the applicant must first get NMPA permission to perform a clinical trial.

The authorization procedure for carrying out clinical trials has been greatly accelerated since April 1, 2019. If the candidate has not obtained a judgment from the Centre for Medical Device Analysis within 60 working days of the date of submission and payment of the clinical trial authorization application, the applicant can begin conducting a clinical trial (on the premise that the contact information and mailing address are valid) ⁷.

Aim of Clinical examination of medical device

Under normal circumstances of use, the latter should determine whether a particular MD: (a) achieved the original goal planned in its design and functions as expected; and/or (b) provided the predicted clinical benefit; and/or (c) demonstrated an appropriate risk/benefit ratio, taking into account the side effects weighed against the advantages to be gained by the device. Each CI can indicate conformity with one or both of the above-mentioned characteristics; however, for pre-marketing and post-marketing CIs, the permissible goals were restricted to the list above. CIs should be created with the understanding that there is a minimal place for hypothetical research in these types of studies. The goal of pre-and post-marketing CIs is to gather information for clinical assessment or post-marketing clinical follow-up (PMCF).

Clinical examination of medical devices

A clinical trial is a systematic examination or research conducted in or on one or more human participants to determine a medical device's safety, clinical outcomes, and/or efficacy. Data collected from the clinical trial(s) performed in a foreign nation or jurisdiction that is intended to be utilized as scientific proof for a pre-market registration application in China is referred to as "overseas clinical studies" in this document. Many pre-market and post-market clinical studies of medical equipment, as well as in-vitro diagnostics (IVD), take place outside of China and produce reliable data. If they fulfill the necessary conditions, data from outside clinical trials can be accepted and utilized in clinical review for pre-market authorization in China.

The global clinical study must adhere to the World Medical Association's Declaration of Helsinki's International Code of Ethical Practice, as well as the recognized standards or other ethical norms, laws, and legislation of the nations where the clinical trial is performed. The sponsor must also ensure that the trial is ethical and scientific and the research subjects' rights, safety, and well-being are maintained.

An international clinical trial should be done in a country with a quality management system for clinical studies to assure high-quality data. Trials should, in general, adhere to local rules or fulfill recognized standards, which may differ in certain ways from China's Good Clinical Practice (GCP) for Medical Devices. The study may be judged to satisfy the GCP standards if these discrepancies do not impair the results' originality, reliability, or predictability, and the subjects' rights and interests are maintained. Clinical trial data from other countries should be genuine, scientific, efficient, and identifiable. Without exception, all information should be provided in its entirety.

The sponsor must guarantee that: (a) the clinical trial's goal is suitable; (b) the desired data are gathered via a scientific and reasonable trial design and methodology; (c) the conclusions is clear, and (d) the subjects' and other relevant persons' rights and interests are not jeopardized.

All three principles must be met for clinical trial data from other countries to be accepted. If any of the standards are not followed, the data will be rejected by the National Medical Products Administration (NMPA). Medical devices vary in terms of their methods of activity in or on the human body, the type and length of interaction with the human body, and the therapeutic outcomes they are intended to produce. As a result, medical devices may have varied hazards and clinical outcomes depending on the demographic. Data from human participants that can be generalized to Chinese consumers will be accepted by the NMPA. The following are some of the aspects that may have an impact on clinical trial data over a wide range of subjects:

Human genetic polymorphism or demographic features such as race, age, and gender are examples of intrinsic factors. Extrinsic factors: such as food habits, environmental triggers, smoking, drinking, illness incidence, uncommon or regional comorbidity, obesity, social and economic situations, religious views, academic background, and medical conformity. When a device is utilized in human beings, intrinsic and extrinsic variables frequently interact and can impact the device's safety and efficacy. The following are two instances of when issues linked to topic differences should be addressed. Example 1: For non-invasive pulse oxygen saturation and pulse rate measurements, a pulse oximeter device is employed. The functioning mechanism depends on pulsatile flow-induced time-dependent variations in optical tissue characteristics. Because the working principle includes the interaction of optical signals with tissues, melanin deposition should be taken into account. The skin tone of the foreign participants and the Chinese population of the study, in particular, may differ. As a result, a bridging clinical trial may be required. Example 2: A genetic illness gene identification in vitro diagnostic reagents kit. Assume that the target genes chosen from human volunteers from other countries are different from those chosen from Chinese ones. In that situation, bridging clinical research of influencing variables (e.g., mutation locations, mutation frequencies of genetic condition genes) in the Chinese target population is required.

Clinical surroundings, medical facilities, investigating officer abilities (i.e., learning curve), and diagnosis and treatment ideas or codes all impact the medical practices in which a clinical study is conducted. Whether the results can be extrapolated to the Chinese target group may be influenced by differences in clinical situations. Clinical experience in other nations, for example, may not apply to patient treatment recommendations in China due to differences in screening and therapeutic ideas or criteria. Under the usual operating protocols of Chinese institutions, some devices may operate differently in outside clinical trials. Additionally, changes in plant-derived and

investigator capabilities or experience may have an impact on trial outcomes, particularly for medical devices that need a professional operation.

If the clinical evidence came from a multi-regional clinical study including Chinese institutions, a breakdown of the case distributions is needed for further analysis. It is suggested that the organization/applicant interact with the medical device assessment authorities ahead of time to achieve an agreement on the adequacy of the foreign clinical information for the medical device undergoing consideration.

The Food and Drug Administration, the European Parliament and Council, and the Pharmaceuticals and Medical Devices Agency are just a few of the medical device regulatory bodies that have released recommendations on the acceptance of data from abroad clinical trials. These regulations are not in contradiction with the NMPA's standards. The International Medical Device Regulators Forum also standardized the standards for accepting clinical trial data from other countries. For doing a clinical examination, trial information can be employed as a supporting data source. Accepting data from medical device clinical trials conducted in other countries is a good way to make good use of existing data. It is critical in avoiding or decreasing recurrent clinical trials, as well as contributing to the faster introduction of medical devices and accessibility of health to them ^[8&9].

Marketing authorization of medical devices in China

The categorization standards for medical devices in China are comparable to those in the United States. The CFDA divides the devices into three categories, as shown in Table 1. The reason for this is that the nomenclature of devices was contradictory under the previous standard, resulting in the same goods having various names or the same names referring to distinct products. In the United States, however, each device will only have one name and product code; various items have distinct names and codes. The EU devices categorization system is based on the 'Directives Rules,' which is a database system linked to an expert group that provides technical support. The CFDA implements three medical device classifications using devices classification rules and 'classification catalogues.' 'When a device has to be categorized, for example, the reviewers will seek classification catalogues first, and if the products do not exist in the catalogues, the reviewers will classify the item using the 'classification rules.'

Banned devices

In exceptional circumstances, the FDA may eventually remove a device from the Federal Register if it gets to decide, based on all available records/knowledge/ knowledge and after having to consult with the suitable classification panel, that a device intended for human use presents deception (such as adulteration or mislabelling) or a risk of illness or injury that cannot be corrected by changing the labelling ¹⁰.

Table 1: Percentage breakdown of medical devices classification levels

Country\Class	Class I devices	Class II devices	Class III devices
US	47%	43%	10%
China	36%	41%	23%

In addition, in the United States, only around 8%–10% of medical devices are categorized as high-risk devices, but in China, over 20% of devices are designated as high-risk devices (see Table 1). The computed tomography (CT) scanner, for example, is classed as Class II equipment in the United States but as a Class III device in China. In China, far too many goods are classed as high-risk gadgets. This not only places a significant financial strain on producers, but it also places a huge significant efficiency pressure on government administration. Class III devices account for 23% of all devices in China, although high-risk and creative technologies account for just 5% of the total

submission of the application. The Chinese medical device registration system is a hierarchical system, see Figure 1. Theoretically, this method should have a fast-processing time and great efficiency, yet it can be sluggish. Although this approach should hypothetically have a rapid processing time and high efficiency, it can be slow. Medical device registration certificates can be issued by regulatory bodies (except at the county level).

China National Standards (GB standards) and professional/industry standards apply to medical equipment in China (YY standards). If medical devices are to be sold in China, they must at least fulfil the criteria of Chinese GB standards or professional standards, or foreign standards such as ISO or comparable. Medical diagnostic X-ray equipment, electrocardiographs, pacemakers, and other medical gadgets still require the China Compulsory Certification (CCC) mark for product safety.

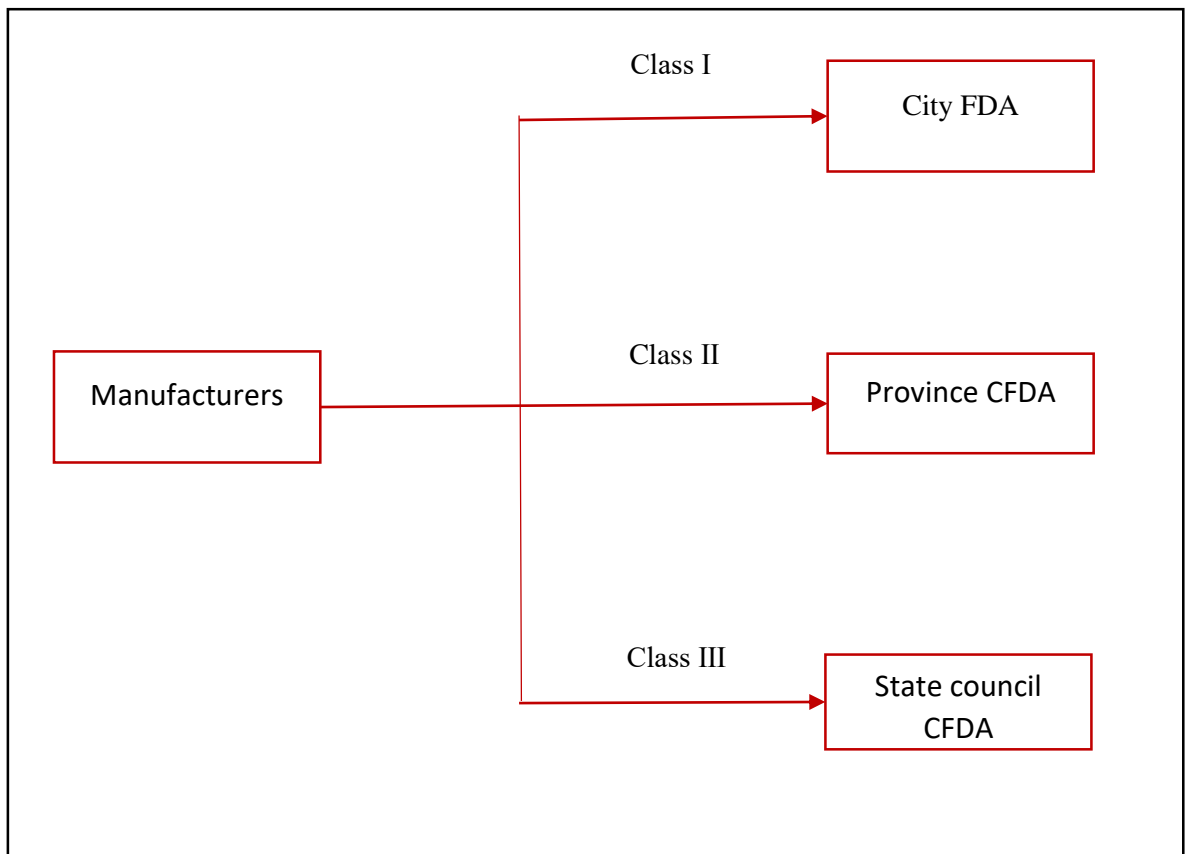


Figure 2: CFDA Registration System

China has built adverse event surveillance systems and data networks, as well as medical device reassessment and recalls, although these systems are still in the works and require further legal backing. The CFDA's objective is to protect patient safety and guarantee that all medical devices on the market are safe and effective. The CFDA conducts random testing for medical device producers and users regularly. The CFDA has built adverse drug events systems to collect all data on patient device surveillance. This encourages medical device professionals to submit any medical device-related information, such as quality difficulties, major injuries, or patient fatalities ^[3].

Harmonization of Medical device regulation

To provide the medical device sector a chance to fully realize its potential, the requirements for medical device clearance must be unified. The Global Harmonization Task Force (GHTF) was established in 1993 with this goal in mind. The European Union, Japan, and the United States, as well as Canada and Australia, are founding members of the GHTF. The GHTF's main goal is to consolidate and unify regulatory procedures through its several Study Groups.

In addition, the GHTF promotes cutting-edge technology and streamlines international trade. The design and publication of harmonized regulatory guidelines is a critical step in achieving the organization's goals.

These guidelines, which were developed by several GHTF Study Groups, can subsequently be implemented by member national regulatory agencies or others. The advice suggests a four-class framework for medical devices based on expected use, which should identify specific device conformity evaluation procedures ^[11].

Medical device as per the social environment context

The medical device company's workforce and earnings are difficult to quantify. Although the manufacture of medical equipment falls under the manufacturing industry group, it is not tracked independently on a global scale (Eurostat databases, OECD). The medical device business employs 15,400 people, according to Eurostat and the OECD. Between 2012 and 2013, the median pay increased by 5% to \$105,000. Earnings are reflecting the increased demand for personnel in the areas of performance and regulatory affairs. In 2013, salaries for quality assurance and quality control experts rose by more than 3% ^[12].

Adverse events reporting

The MOH and the CFDA manage China's post-approval monitoring system, which is carried out at the regional level by provincial health departments. Regional autonomy in conjunction with a tiered centralized system is a fundamental feature of Chinese post-approval monitoring. When adverse medical device occurrences occur in a certain location, the first line of defence is the provincial health departments and regulatory bodies. The National Centre for ADR Monitoring is part of the CFDA and is in charge of collecting, aggregating, and evaluating adverse drug events reports from all provinces of the country. Each province and area also have its own ADR Department, which has better and faster access to local data than the National ADR Centre but limited analytic capabilities. This regional autonomy might lead to quicker reactions to unfavourable occurrences and aid in the implementation of policy reforms. Around the same time, the CFDA and the National ADR Centre's central authority enables regional collaboration and serves as a platform for uniformity ^[7].

International function

The MDA is a key player in Europe and has been at the forefront of transformation in the EU. The Task Force of the Global Harmonization (GHTF), which is analogous to the pharmaceutical ICH (International Conference on Harmonization), has emerged in the device industry. It is at a prior stage of development than the ICH and is less organized. Its most recent initiatives have focused on device nomenclature as well as post-market surveillance and counselling ^[13].

Regulatory bodies in the developed world

The Therapeutic Products Directorate's Medical Devices Bureau is the regulatory body in Canada that requires Class III and IV manufacturers to submit a Marketing approval Review Document (a summary of safety, effectiveness, and clinical studies). In Australia, the Therapeutic Goods Administration (TGA) oversees medical device approval, which is identical to that in Europe. The Korea Food and Drug Administration (KFDA), Korea's regulatory body, mandates higher-risk device makers to submit a Scientific File, which includes type assessment by a third party and clinical studies. A compliance review is also required to achieve Korean Good Manufacturing Practices certification (through a third-party entity that collaborates with the KFDA). Singapore now needs product registration, although devices that have previously been authorized in that other markets, such as the United States, Canada, or Europe, may have their registration procedure shortened ^[14].

Post-marketing surveillance

The activity of monitoring the safety of medical equipment after it has been launched on the market is known as post-marketing vigilance (PMS). Post-marketing supervision guidelines are a set of procedures and activities for monitoring the safety and efficacy of medical devices after they have been approved for use. These activities are intended to provide data that may be used to immediately identify malfunctioning devices and other safety issues, as well as correctly evaluate device efficiency and clinical outcomes in the real world. Customers complaining and corrective and preventative action (CAPA) resulting from customer complaints are handled as part of post-marketing monitoring ^[15].

New medical device: A novel medical gadget is one that does not have any precedent devices that have been authorized by regulatory authorities.

Predicate device: A Predicate Device is a device that has been approved by the Regulatory Authority for the first time and is the first of its kind.

Authorized agent: Is a person, corporation, or company was chosen by the Manufacturer to import Devices for sale and distribution in countries other than the manufacturer's home country and to serve as the initial point of contact between the Competent Authority (CA) and the Medical Device Company.

Manufacturer: Manufacturer refers to the natural or legal person who is responsible for the design, manufacture, packaging, and labelling of a device before it is placed on the market in his or her own name, regardless of whether these operations are performed by that person or by a third party on his or her behalf ^[16].

CONCLUSION

The new regulations aim to improve the safety and efficacy of medical devices in the Chinese market while also addressing flaws discovered in the application of medical device regulations by many medical device makers. It might be beneficial as a regulatory tool for approving the placement of a product on the market. For every type of medical equipment to be commercialized in any nation, authorization is required. Medical devices are controlled in an unusual way by the National Medical Product Administration (NMPA) and national authorities. Where marketing authorization is given by the appropriate authority of the particular nation, the NMPA ensures compliance with quality and safety criteria. To achieve the top objective of improved performance and safety assessment of newly create devices for the treatment of various diseases, efforts from all players during clinical examination, such as investigators, device manufacturers, and government regulators, are required.

Patient risk should be minimized for creative high-risk devices while preparing for a rewritten medical device legislation by limiting the market release of novel high-risk devices with insufficient clinical evidence to physicians with the requisite training and skills. The new regulation should require premarket clinical effectiveness and safety demonstrations, ideally utilizing randomized controlled trials and a transparent clinical revival. In the current situation, unique research methodologies for the assessment of novel devices may be required.

The new regulation reflects the Chinese authority's attempts to improve and maintain a functional regulatory system for the medical device industry. The Chinese authority has issued new regulations, which cover different aspects of the medical device regulatory system, such as device categorization and registration, manufacturing and distribution monitoring, and so on. The Chinese medical device market will become more dynamic incoming future of the new regulations more robust regulatory requirements.

In the future, further in-depth study on this issue will be conducted, some legislation and policies still have to be changed, and more research is needed to better understand changing market situation, which should lead to continuing policy improvement.

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