Medical Device Regulatory Requirements for Mexico

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우리에게 잘 알려지지 않은 새로운 남미의 Mexico 의료기기 시장 진입에 따른 규제에 대하여 해외 제품인증 전문기관인 (주)ITC인증원 LA 지사가 법률적 요구 및 규제사항에 대하여 정리하였다. 본 자료가 Mexico시장으로 의료기기를 수출코자 하는 기업에 도움이 되는 자료로 활용되기를 기대한다. 인증 진행시 요청되는 보다 자세한 내용은 (주)ITC 인증원으로 문의하기 바람

– 편집자주 –

Mexicohas many opportunities for successful business because it is located right next to the U.S. According to the reports, Mexico is the 2nd largest medical device market in Latin America just behind Brazil. Mexico has a population of about 112 million people. They receive health care and medical treatment from the Mexican government and private institutions. The medical devices used in private and government health institutions have to be approved or registered by authority "SSA" (Secreatria de Salud).

SSA as a secretary of health, it monitors and controls the private and government health institutions. The SSA has many functions for the control and monitoring of medical devices and relevant products that are applied to human body, preserving and ensuring the public health and safety. These areas include:

* Drugs and Health Technologies Bureau
* Products and Services Sanitary Control Bureau
* Environmental Health Bureau
* Publicity Sanitary Control Bureau
* National Public Health Laboratory

Mexico is a developing country, looking forward to improve the quality of life through better health care. Unfortunately, the major cause of death in Mexicois various diseases. Among many diseases, the cardiovascular disease is the main cause of death in Mexico followed by the Malignant Neoplasm's. This is one of the reasons why Mexico is in huge demand for new medical devices, new health care products and new treatments.

The health care system of Mexico is divided in two sectors, the private sector and public sector.

Public sector:

Health care services provided by the public sector by the government at low cost. These services are given to the workers of private companies, state workers and their families. Mexican government supports the public schools students providing health care services at a low cost. This public sector is divided in 3 different areas.

a. IMSS (Instituto Mexicano del Seguro Social)

IMSS is the Mexican Institute of Social Insurance which is in charge of the medical system in general. They provide health care for people who work and are registered with the federal bureau and for students wide in Mexico.

b. ISSSTE (Instituto de Seguridad y Servicios Socioales de los Trabajadores de Estado)

ISSSTE is the Institute of Secure and Health Services for the State Workers which provides health services only and exclusively to the state workers and their families, people who work for the government, the areas and services provided by the government.

c. PEMEX, SDN, SM

PEMEX, SDN and SM work together as a team. PEMEX is the government institution which provides health care service to all of its employees. SDN provides healthcare service for veterans and the ARMY, and SM provides healthcare service for NAVY.

Private Sector:

Independent hospitals and health organizations which provide services to anyone who can afford the costs, do not receive any economic support from the Mexican government. However, they are equipped with the top quality medical devices and provide the best service to their patients.

There is some information required to get the license for the market clearance. The required information is very important because they are used to classify these products intothree different classes according to its level of risk. The risk level of the product is determined based on the information provided. There are three categories; class I, class II and class III. They are explained below:

Class I

1.1– All the procedures and items that are known to be used on medical practice

1.2– The procedures and devices have been proved and tested on their efficacy and security

1.3– All the devices and items that do not require to be inserted and kept in the human body

Class II

2.1– All the procedures and items that are known to be used on medical practice

2.2– All the devices either electronic or non-electronic that are required to work inside the human body by invasiveness, but remain inside less than 30 days.

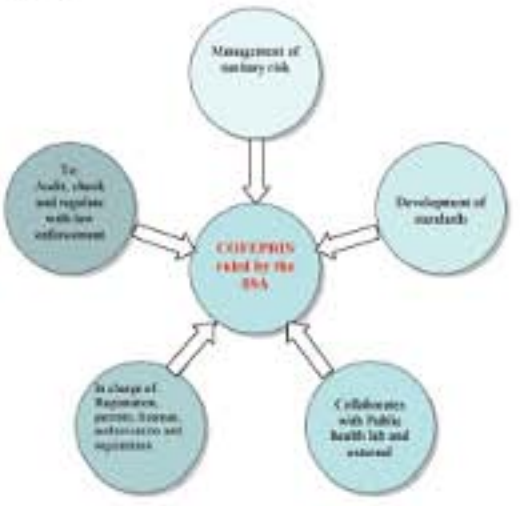
Class III

3.1– This is the classification for the new devices that have been recently accepted by medical practice.

3.2- Any device introduced and kept in the human body that has to remain inside human body for at least 30 days or more.

COFEPRIS (Comision Federal para la Proteccion contra Riesgos Sanitarios)

COFEPRIS is the Federal Commission for Protection against Sanitary Risks, this is an organization controlled by the SSA which regulates the norms and specifications for a medical device or treatment to operate in Mexico. This organization is specialized in the sanitary norms; the procedures and the importation and exportation of products, and medical equipments, prosthesis, diagnostic reagents, dental products and everything related to the human health care including organs transplantation and al the materials used in the process. In other words, all medical procedures, materials and medical devices need to be approved by COFEPRIS to get the authorization of the SSA to be used and distributed in Mexico.



SSA registration requirements:

All medical products and devices that contact the human body are required to be registered with the SSA (Secretaria del Salud) to be imported into Mexico. Registration is required for all products related to health caresuch as surgical devices or materials of any kind, implantable prosthesis, dentistry products and materials used.

How to register:

It is necessary to fill out an application form and submit to the authority in Mexico

1. Complete information about the representative/distribution company including its name, address and telephone number.
2. Product manufacturer's information in its country of origin, such as telephone and fax numbers.
3. Name and signature of the representative/person responsible in Mexico.
4. The copy of one of the following documents regarding to the Mexican distribution representative: Operation authorization/ certification documents or sanitary authorization or certification of a visit from the Secretariat of Health for Verification and authorization.
5. Copy of the authorization of the person/persons responsible for the Mexican representative's office. (It is required by law that all stores or establishments related to medical and chemical products must have a chemical engineer or physician responsible.
6. Detailed information according to the product to demonstrate that it fulfills with the requirements and characteristics as authorized in the country of origin. This information must be in Spanish and include the following:

* The use or purpose of the product/device
* Quantitative or percentage formula used in the product/device
* Technical specifications of the product/device, procedures used it and evaluation's final report.
* A certificate specifying the sterilization technique used for the product/device and the results of the test.
* Clinical information proving its effectiveness and safety
* Description of the package for the products and the proof that it keeps the product/device sterility while in it.

7. Original and copy of the proposed label, in Spanish, that must include the following information:

* Commercial name given to the product/device.
* Intended use and warning label.
* Serial number or lot number.
* Sanitary registration number obtained from the SSA.
* Company's name and address of manufacturer.
* Company's name and address of distributor.

8. A brief description of the product/device's manufacturing process
9. Description of the components, structure and function of the product/device.
10. Laboratory tests verifying product/device's specifications under the signature of the responsible person in a foreign or local institution, including:

* Certificates of the physical-chemical, micro-biological, and biological tests used in the finished product/device.
* Stability proof.

11. Index references
12. Approbation of the FDA (authorization in the U.S.) to work with sanitary products/devices
13. Good Manufacturing Practices certificate by the country of origin authority (FDA for U.S.)
14. Original analysis certificate from the manufacturer, in company's stationary, and signed by the chemical or sanitary responsible.
15. Original and 2 copies of the registration fee payment receipt.

Since Mexico does not have all the resources to test everything to comply and verify the effectiveness of allmedical devices, they have started to work together with the FDA, which assists and help Mexico with the information to verify compliance.

The registration and approval scheme is similar with CE/MDD and FDA regulations. In order to facilitate the acquisition of SSA approval the manufacturer from abroad can approach strategically. They can consider concurrent application of certification either CE/MDD or FDA together with SSA approval. If they apply two certifications together, they can save the time and cost for the preparation of technical documentation and testing. MD

제2회 중국 국제 의료기기규제 포럼 개최 및 ITC인증원의 발표

중국 국제 의약품 정보센타가 SFDA의 승인을 받아 "국제 의료기기 규제 포럼"을 6월 7일부터 10일까지 개최했다.

중요 내용은 의료기기 관리 규정 및 방침에 대한 일반인의 접근성을 용이하게 하고, 국제 의료기기 관리 기관 및 평가 기관간의 협력 및 정보 교환, 생산 기업 업무 방식의 표준화, 기업과 정부 기관 및 기업들 상호간의 의견교환의 원활화, 새로운 기술 표준의 적용 및 기술적인 달성을 통한 의료기기의 안전성 및 효능을 강화하는데 기여하기 위하여 총 8개의 분야로 구분하여 포럼이 진행되었다. 중요 포럼 분야는 영상장비, 심장 관련 신개발 제품, 안과장비, 체외진단장비 분야가 주축을 이루었다.

ITC 인증원은 "중국 국제 의료기기 규제 포럼"당국으로부터 의약품을 포함하는 첨단 복합 의료기기 분과에 강의를 요청 받아 심혈관 스탠트로서 약품을 포함하는 복합의료기기에 대한 발표를 ITC 인증원 한국 본사의 심상우 본부장이 진행을 하였고, 진행의 지원은 ITC 인증원 북경 대표부의 이영팀장이 하였다.

발표 이후 많은 참가자로부터 약품 포함 복합 의료기기에 대한 제품인증 특히 CE 인증에 대한 질문이 있었고 그에 대한 답변을 전달하였다.

이번의 의료기기 규제에 대한 국제 포럼이 아시아 및 전 세계 의료기기 산업계 및 관리 당국의 수준을 한 차원 높이는 좋은 계기가 되었다고 평가한다. MD