

Panama, Republic of Panama Ministry of Health



Ninth Global Harmonization Task Force Meeting
Singapore, 15th of May 2002

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Legislative Chamber

Law 1

10th of January 2001

About Medicines and Other
Health Products



Law 1, January 2001

- Regulates the fabrication, introduction, distribution, comercialization, publicity, sanitary registration, and quality control of medicines, medical devices, antiseptics and desinfectants, plaguicides, cosmetic products and other products related to human health



National Registry of Suppliers

To homologate selection, admission,
suspension and exclusion criteria

Ministry of Health, Ministry of Finance,
Social Security, Ministry of Commerce,
Chamber of Commerce, Comptroller

Comercial license, operation license, sample
or catalog of products, finance statement



Interinstitutional Technical Committee

- Interdisciplinary group that homologates the technical specifications of medicines, medical devices and equipments that are used in the public sector



- Technical specification card: is the description of the medical device, including attributes for quality assurance
- Sanitary Registration: is the authorization that the Ministry of Health gives a company for the importation and/or commercialization of a medical product or devices, after the correspondent evaluation



Law 1

- Article 44 and 45

The Ministry of Health with collaboration of the Consultive Technical Committee will regulate the medical devices that require sanitary registration or technical criteria.

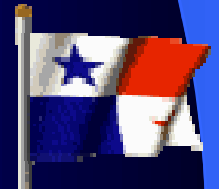
Sanitary registration of these products will have a duration of 10 years and can be renewed



Executive Decree 148

9th of August, 1999

- Sanitary Registration for reactivities, material, equipment and biological products used in laboratory for diagnosis
- Central Referral Laboratory under the Center for Biomedical and Biotechnology Research of the Gorgas Commemorative Health Research Institute
- Gives criteria for registration, evaluation for any new laboratory product



A Medical Devices Regulation Proposal



Medical device' means any instrument, apparatus/implement/machine, appliance, implant, reagent/calibrator, software, material or other similar or related article, whether used alone or in combination to be used for human beings for the specific purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation/mitigation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury,
- investigation, replacement, modification, or support of the anatomy/body structure or of a physiological process
- supporting and sustaining life,
- control of conception,
- disinfection of medical devices,
- providing information, by *in vitro* examination of specimens derived from the human body

pharmacological, immunological or metabolic means, but which may be assisted in its function and which does not achieve its principal intended action in or on the human body by such means.



Classification

- Class I: Non-invasive or invasive medical devices with very low risk
- Class II: Medical devices with a low to moderate risk.
- Class III: Medical devices with moderate to high risk.
- Class IV: Medical devices with high risk



Sanitary Registration Class 1

-Inscription

- -GMP, ISO, Declaration of Conformity (CE)
- -Certificate of free selling in country of origin
- -Sample or catalog
- -Labels and inserts



Sanitary Registration Class II

Same requirement as Class I plus
Certificate of analysis (when needed)
Sterilization techniques (if applicable)
Scientific studies of effectivity and security



Sanitary Registration Class III

- All previous requirements, plus
- Description of manufacturing and packing materials
- Summary of Security, Effectivity, Comercialization history in other countries (number of sellings, fails and recalling)



Sanitary Registration Class IV

- Same requirements plus
- Risk assessments and Risk Reduction Plan
- Production Protocols
- Detailed Clinical and Preclinical Studies



Surveillance System

- Post commercialization surveillance system
- To minimize health risks
- Obligatory notification of failures, deterioration or adverse reactions
- Patients, health providers, manufacturers or
- suppliers, maintenance personnel



Surveillance System

- Special system for class III and IV products
- Periodic and unannounced surveillance and sampling
- Entities must comply with preventive maintenance systems
- Each health installation must have its vigilance system
- Registry of distribution, complaint management, notification of adverse events,
- recallings



Pending Issues

- Management of donations
- Refurbished equipment





Thank you,



[Ministerio de Salud](#)

