



Cuban Regulatory Program for Medical Devices

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Cuban Regulatory Program for Medical Devices



Establishment

In March of 1991 was established the Medical Device Sanitary Register, settled down by means of Ministerial Resolution of the MINSAP.

In January of 1992 was created the **National Control Center for Medical Devices**, beginning the tasks for the creation of the Cuban Medical Devices Regulatory Program.



Strategies.

- ✓ Development of the national industry.
- ✓ Analysis of the international regulatory tendencies.
- ✓ To guarantee the safety and effectiveness of the medical devices used in the SNS.
- ✓ Stage by stage transit
- ✓ Special attention to radiodiagnostic and radiotherapy devices
- ✓ Development of the legal and technical base



The Cuban Regulatory Program for Medical Devices and GHTF's recommendations

- Introduction of standards for specifications or testing assays for medical devices.
- Inclusion of all risk classification rules for Medical Devices.
- Establishment of experts panel.
- Definition of the exceptional for new medical devices, and its treatment.
- Introduction of the quality assurance requirements according to ISO 9000, with the step by step of requirements to accomplish.



The Cuban Regulatory Program for Medical Devices and GHTF's recommendations

- Manufacturer's inscription like technical stage more than administrative stage.
- Regulations in order to vigilance systems and postmarker reports.
- Introduction of substantial equivalence with other registered devices.
- Establishment of the Consensus Standard Regulatory List



Improvement of the Medical Device Regulatory Program



Is foreseen will be culminated in 2003 with the conclusion of the revision, amplification, modification and introduction of new concepts. Considering the requirements in accord to the actions that involve American area.



Our Regulatory System is based on GHTF's recommendations and our conditions.

- ✓ Role of Standards and assessment of medical devices (GHTF SG1 N012R10)
- ✓ Quality requirements (GHTF SG3 99-8)
- ✓ Postmarker Surveillance (GHTF SG2 N21R8, N7R1, N8R4, N9R10)
- ✓ Essential principles (GHTF SG1 N020R5)
- ✓ Labelling for medical devices (GHTF SG1N009R6)



Since its creation, the Cuban Regulatory Program for Medical Devices has passed for 4 stages.

- 1st stage**
(1991-1993)
- Demand to the manufacture about the presentation of a documental summary.
 - The main national medical devices had the technical scientific backing of the Sanitary Registration.

- 2nd stage**
(1993-1995)
- Technical tests, preclinicals, and authorization of the clinical trials
 - Contribution to the development of the manufacture's quality systems
 - Export and Extension of Registration Certificate
 - 56 registered national devices.
 - Cuba attend to GHTF's meetings.

- 3th stage**
(1995-1998)
- Quality control of the radiodiagnostic and radiotherapy devices
 - Beginning of the emission of Export Certificates
 - Develop of the Internal Quality System of CCEEM.
 - It concludes with 102 registered national devices



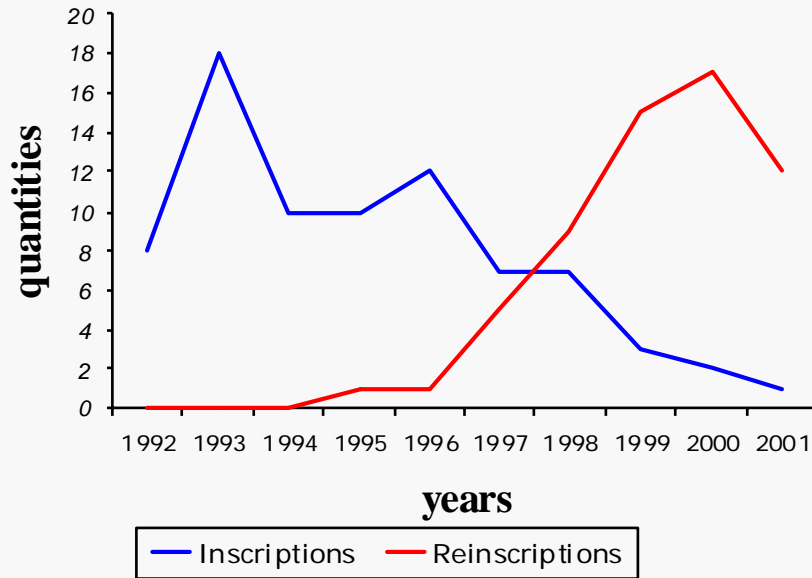
4th
stage⁽¹⁾
(1998-2001)

- 304 registered devices
- Performance of projects with international organisms (PAHO, IAEA), for the improvement of quality in Radiology.
- Released the Audit service to the following of Radiotherapy installations, and doing systematically the extern audits to radiotherapy services.
- Establishment of the Ministerial Resolution number 218, about the Safety Committee for Medical Devices.
- 42 adverse events reports and 6 safety alerts
- Improvement of the scientific information services

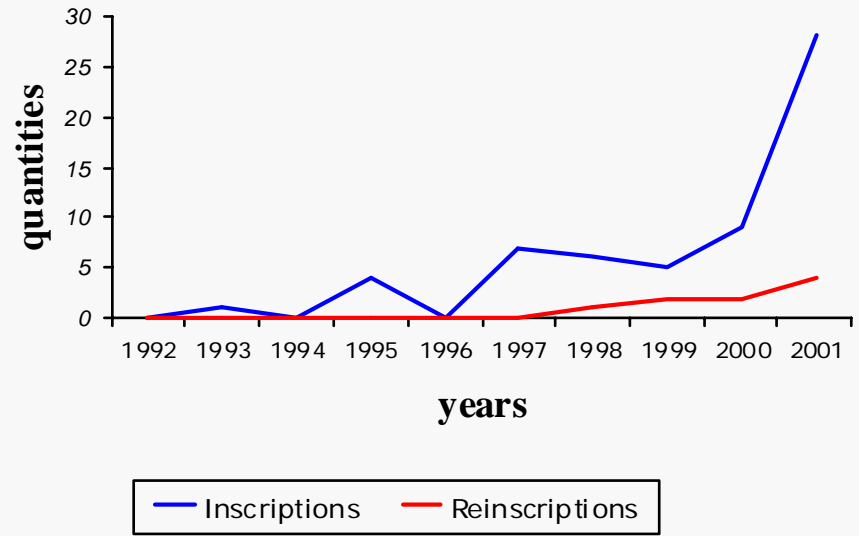


Inscription and Reinscription Processes

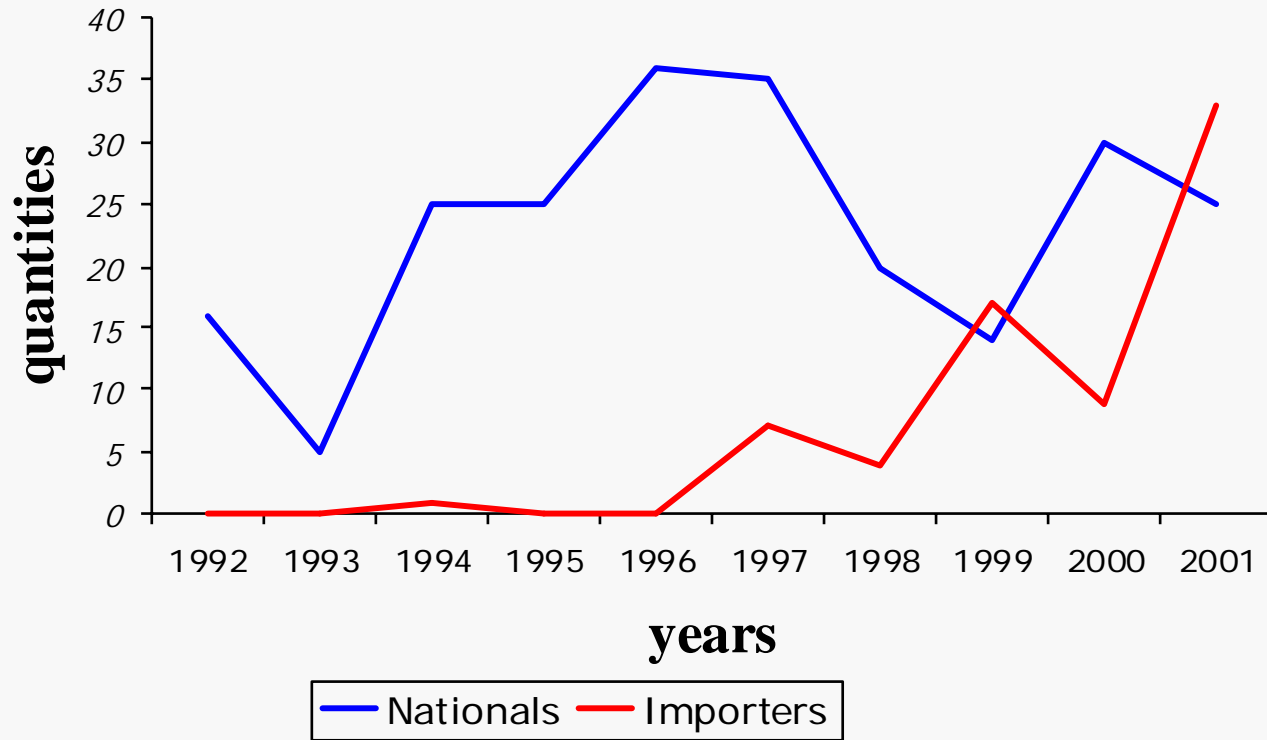
Nationals



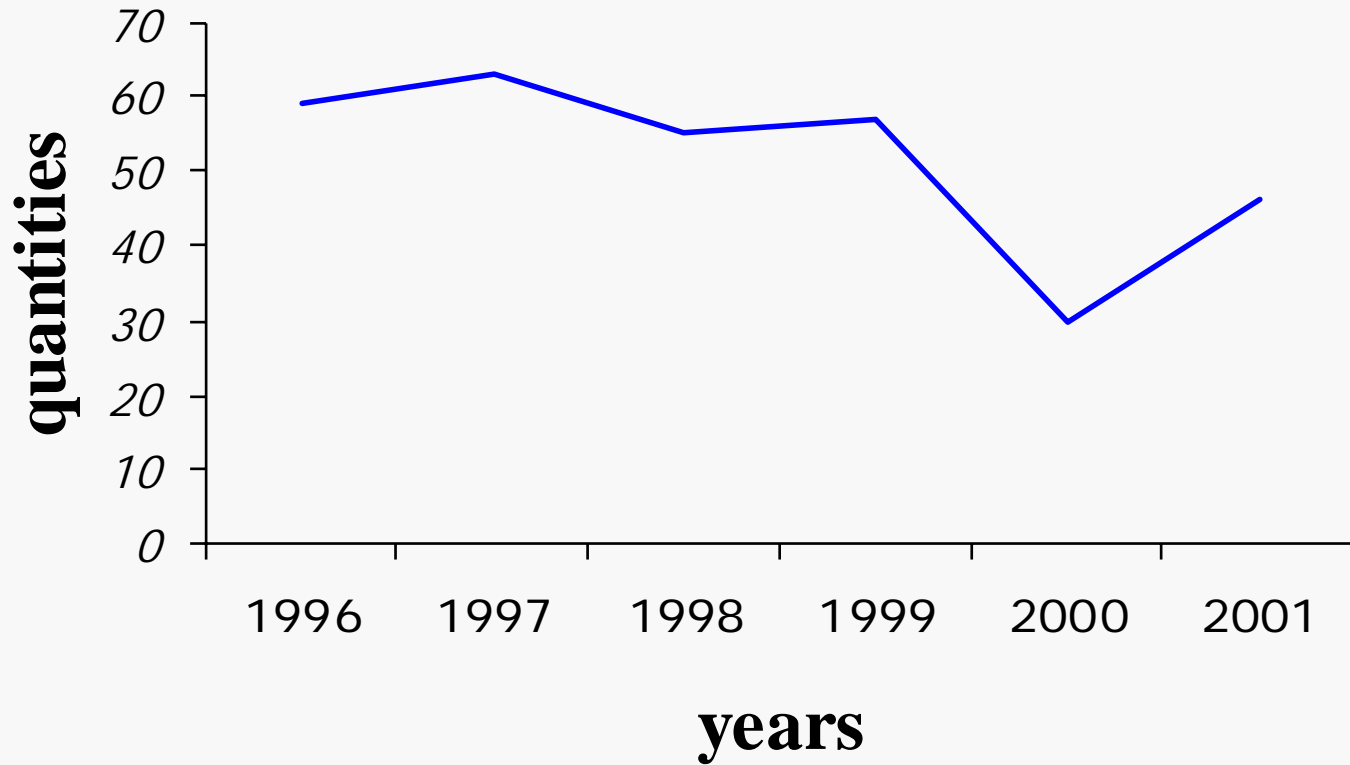
Importers



Medical Devices Register



Certificates for Medical Devices Export



— Certificates for Medical Devices Export



In this moments the Program pass by its **5th stage**, that include:

- Increase the knowledge about the Medical Devices Sanitary Register necessity and the accomplish with the Regulatory Program.
- Strengthening of infrastructure for essential assays to the safety and effectiveness.
- To conceive the Manufacturer Inscription Process like a market control guide.
- Elevation of medical devices control and following in the National Health System (NHS)



- Vigilance development with the establishment of the Manufacturer's Report and continuation of the Mandatory User Report of Adverse Event, reducing all risks associated to medical devices.
- Go ahead the integration of GHTF's recommendations through our own regulatory program.
- Continue the collaboration inside PAHO and IAEA; to keep the exchanges with the GHTF working groups and participate in ISO/TC 210.
- Conclude tasks associated with the CCEEM Quality System in order to obtain the Accreditation for 2003.



- Elevation of the regulatory requirements and Audit and Inspection fortification in the manufacturer's quality system.
- To increase technician, physician and physicist training from the introduction of quality guarantee systems.
- Specialists continuous training in order to increase their scientific and technical level.
- Development of tools for raise Informatization and Knowledge Management levels.



Cooperation and Harmonization



- Colaboration with PAHO and active participation in the America's Meeting; extention and revision of the regulatory documents, regarding the requirements in agreement to actions that involve the America's Region.
- Promotion of activities that influence on exchange actions in the America's Region, and to facilitate the knowledge throught the mutual recognition agreement, interest point to countries of our Region.



Meeting for the X Anniversary of the
Cuban Regulatory Agency for
Medical Devices

Havana City, Cuba.

International Press Center

July, 30th, 31th , August 1st 2002



On the occasion of their **X Anniversary**, the CCEEM invite you to take part in the **Meeting** to discuss and expose some experiences from the regulatory agencies for the medical device of the Region, attend to the directives from 42 Directive Council for the PAHO, hold in September 2000.



Objectives of the Meeting:

- Analysis of the results for ten years of experiences and prospects for the CCEEM.
- Analysis of the results from Cuba-Canada exchange.
- To contribute to the exchange, for an integrative process and of mutual recognition among the regulatory agencies of the Region, in agreement to tendencies of the GHTF and the regional interests.
- Presentation of the monograph about the Cuban Regulatory Program for Medical Devices.
- Up to date about the scientific and technical level in the main topics of the Meeting.
- Presentation of new technologies and Medical Devices.



We're waiting for you in

Havana City
Havana City

Havana City
Havana City

Thanks

