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PROLOGUE

Regulation of the sale of medical devices in a country has been shown to reduce the problems, often serious, from inadequate and defective equipment.

More countries are now taking an interest in such regulation as health costs escalate and more sophisticated devices are used in diagnosis and treatment.

This seminar was designed to introduce Latin American and Caribbean health officials to Canadian, U.S., and European experiences with the regulation of medical devices and to develop recommendations for regulations in the participating countries.

Twenty-five participants from Argentina, Brazil, Canada, Chile, Costa Rica, Cuba, Ecuador, Holland, Jamaica, Mexico, Spain, Uruguay, and USA, attended the seminar. The conclusions and recommendations are listed in section VII.

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INTRODUCTION

In 1983 informal discussions were held between the World Health Organization (WHO), the Pan American Health Organization (PAHO), the Center for Devices and Radiological Health (CDRH) of the U.S. Food and Drug Administration (FDA), and the Bureau of Radiation and Medical Devices (BRMD) of Canada. These discussions resulted in the International Conference of Medical Device Regulatory Authorities (ICMDRA) in 1986.

The Conference, provided an international perspective of problems, issues, policies, and framework for national management of medical devices. It was clear from the discussions that developing countries would benefit by an increased exchange of information on health technology. One strategy proposed by ICMDRA was seminars for medical device regulatory agencies.

Devices which are not safe and do not function satisfactorily are hazardous. They cause morbidity and mortality in patients, increase health care costs, and may harm persons using the device. These problems stimulated the introduction of device regulations in industrialized countries. Regulating medical devices in a country helps to ensure that only those medical devices that are safe and effective are available for sale, distribution, and use.

The "Seminar and Advisory Group: Health Technology Regulatory Policies" analyzed different policy instruments used to regulate medical devices, examined the Canadian, European, and U.S.A. experiences in medical device regulation and developed recommendations for co-operation and future action.

I. OBJECTIVES

The general objectives of the Seminar and Advisory Group were to assess the status for regulation of medical devices in the Region, to explore strategic options for improving regulatory instruments, and to develop a basic program for technical cooperation among countries.

A. Seminar

- Analyze problems of safety and efficacy of health devices in the Region.
- Assess the actual status of regulatory agencies and their functions in the countries.
- Explore the appropriateness of different regulatory approaches to the social, economic, and political situation of different countries.

B. Advisory Group

- Identify needs and possible strategies for information exchange on regulation.
- Develop a basic program for technical cooperation among countries to improve regulatory functions.

II. PERSPECTIVES ON REGULATION OF MEDICAL DEVICES

A. Overview of Regulatory Policies

Protection of the public from fraud in the marketing of food products represents one of the earliest forms of government regulation of commercial enterprise.

There are references to such laws in the Bible. Under Roman Civil Law, the rules governing the sale of food were as complex and specific as any laws that exist today.

Most of the consumer laws, i.e., laws to protect the consumer, which are in force today, were developed and implemented as a result of fraudulent practices, the occurrence of tragedies, and pressures from the general public.

In Canada, the Food and Drug Laws were ushered in by the passion of Canadians for whisky. A parliamentary committee decided that it was not liquor, but bad liquor, that ought to be banned. It would have been an obvious case of mixed priorities to ban the adulteration of whisky without a similar ban on the adulteration of foods and drugs. The Food and Drugs Act which we have today in Canada was the result.

Regulations are important and pervasive instruments of national and international policy.

Governments have a variety of means at their disposal to control, and reduce hazards. These mechanisms can be regulatory, educational, or economic and their choice and application will ultimately be determined by the socio-economic forces that determine the government's political policy.

Guidelines are more easily adaptable than regulations and can be quickly revised to reflect changing technology or business realities. Additionally, they can be ignored by industry in favor of methods of compliance which the industry may view as more appropriate.

It has been suggested, from time to time, that regulation is an unnecessary barrier to new product innovation. In this instance, innovation is considered to be the exploration of new

technology and the development and introduction of new products. The choice is between scientific rationality or personal freedom.

Modern choices in regulatory policy are seldom simple. Neither is the choice among competing options in any specific regulatory decision.

Dr. Henry Kissinger once suggested that "the central moral problem of government has always been to strike a just and effective balance between freedom and authority".

B. Constitutional Aspects of Regulatory Policies

C. Regulation of Medical Devices in Europe

A survey, addressing the issues raised by the regulation of medical devices in Europe, identified four main areas of concern:

- Definition of quality
- Problems concerning quality
- Analysis of Law systems
- Self-regulation

The concept of quality must be taken broadly to include all the problem areas - the implant, the procedure, and the recipient. Regulators may not be able to influence all aspects of device use, but improving the device itself improves the overall chances of successful use.

Using implanted hip joint prostheses as an example, the life cycle model can be broken into five stages:

- . Design and development are usually in house at the manufacturer and in university departments. These are not normally regulated by government.

- . Clinical trails are the next stage; these are controlled by regulation in some countries and by university and hospital ethics committees in most places.
- . Pre-market evaluation by the regulatory agency may be a next step, resulting in general marketing of the device if it is found adequate.
- . Good manufacturing practice inspections will usually be required to ensure that the device is produced properly and consistently.

Problems that may arise must be investigated to see whether modifications are required and ongoing evaluation will further define the products expected performance.

Analysis of Law Systems

In the United States, the FDA concentrates on clinical trials and market approval, good manufacturing practices and problem reporting are mandatory.

In Great Britain, there is a voluntary registration of manufacturers who must comply with the applicable "Guide to Good Manufacturing Practices".

In the Netherlands, the act has only been implemented for rubber-condoms.

The European Community countries will all have to comply with the European policy concerning quality regulation of medical devices which is now under discussion.

Two European institutes will be producing standards: CEN and

Two European institutes will be producing standards: CEN and CENELEC. If a manufacturer is allowed to put the CE- mark on his product he will be able to put his product on the market in any other European community country.

Regulatory Models

Four possible "Regulatory models" are proposed:

Self discipline, the health care professional himself decides on his own behavior.

Self control, the standards are formulated by a group of health care professionals as in consensus development.

Self regulation, requires "enforceable rules".

Government regulation is enforceable by law.

Conclusion

The present law systems for quality regulation of medical devices are complex and not always very effective. The concept of quality should include the quality of the implant itself, the abilities and knowledge of the surgeon, and the condition and age of the patient.

D. Regulation of Medical Devices in Spain

1. Medical devices are controlled under the General Health Law which requires:
 - marketing authorization or compliance with homologation
 - acceptance of inspections of manufacturing, storage, and control procedures

- reporting adverse effects and government participation in follow-up
 - prior approval of advertising
2. Clinical trials in Spain are required for new implants; trials are controlled:
- 2.1 General (General Health Law 14/86)
- Patients must be informed of procedures that are part of a research project.
 - The procedures may not increase risk to the patient.
 - Patient, doctor, and institution must give consent.
 - National Health Service Hospitals are subject to inspection.
- 2.2 Specific (Royal Decree 944/78)
- Pre-clinical data must support probable safety.
 - Human rights and accepted ethics must be respected.
 - Only fully qualified researchers may conduct research.
 - An independent committee must evaluate the results.
3. There are a series of specific regulations for particular devices.
4. Clinical implants and sterile materials are two areas where the Administration needs to improve its efficacy. At present

the pressures of medical practice force authorizations to be issued while health registration is still under study.

5. Departments involved in Evaluation and Control:

The overall authority is the Ministry of Health and Consumer Affairs. Organization, planning, coordination, authorization, and registration are undertaken by the General Directorate for Pharmacy and Medical Devices.

The General Sub-Directorate for the Evaluation of Medical Devices is charged with evaluation, authorization and registration whereas the General Sub-Directorate of Pharmaceutical control is responsible for inspection, good manufacturing practice enforcement and post-market surveillance.

The General Sub-Directorate for Pharmaceutical Organization and Assistance organizes the supply of medical devices to the National Health Services.

The Carlos III Health Institute checks quality control and compliance with technical specifications.

There is collaboration with the Ministry of Industry and Energy, the Centre for Industrial Technological Development, and the Spanish Association for Standardization.

Assistance is solicited, as required, from hospital, scientific, and professional experts.

E. Regulatory concerns in Specialised Health Service Fields

1. Maintenance

2. Pharmaceuticals

Guidelines for the regulation of pharmaceutical products have been developed at the international, regional and national levels. The implementation of the regulations should be entrusted to a single agency with the capability to:

- evaluate information on the safety, efficacy, and quality of new and marketed products;
- inspect establishments for compliance with good manufacturing, storage, and dispensing practices;
- analyze samples of products; and
- carry out post-marketing surveillance.

However, only in a few countries in Latin America is the responsibility for drug regulation concentrated in one agency. For historical reasons, the laboratory is frequently part of a semi-autonomous national health institute, whereas the drug registration unit is a department of the health ministry. This separation has adversely affected the development of regulatory and control activities based on public health priorities. Instead, one frequently sees laboratory staff dedicated to the laborious analysis of individual products, often with complex compositions such as multi-vitamin preparations, submitted by the producers for registration purposes. Scarce and costly resources should be better utilized through a cost-effective sampling program for monitoring the quality of the drugs that are actually being sold.

Another critical problem is the lack of expertise within the ministry that is required for a thorough evaluation of the

products submitted for registration. This has been satisfactorily addressed in some countries by the establishing advisory committees that call on local experts to evaluate drugs within their area of specialization. The development by such committees of pharmacological guidelines for drug approval has been found to improve the transparency of the registration process.

The WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce is being increasingly utilized by developing countries as a mechanism to control imported drugs. Through the Scheme, the participating Member State certifies to the authorities of the importing country that:

- a specific product is authorized for sale or distribution within the exporting Member State;
- the plant in which it is produced is subject to inspections at suitable intervals to establish that the manufacturer conforms to WHO's recommended Good Manufacturing Practices (GMPs).

The Scheme also provides for information on veterinary

Post-marketing surveillance activities are practically non-existent. However, authorities in a few countries are becoming aware of the importance of this aspect of drug regulation and are developing programs that will start to address this area.

3. Dentistry

In the Americas, only the United States and Canada effectively regulate dental materials and equipment.

National standards have been developed in some countries and other countries require compliance with International Standards Organization (I.S.O.) or American Dental Association standards.

Classification is mainly according to the "Customs Council", but how much is applied to monitoring imports and exports is questionable.

Experience has shown that it is not possible to accept all manufacturers claims without independent testing to check compliance with specifications.

Infection control is an area where quality control and standards are required for disinfection and operative procedures. This is particularly critical with new

technologies such as lasers, ultra-sonics, etc., that are being introduced into dentistry.

General acceptance of reasonable standards is required and this must be accompanied by an effective inspection program that will ensure compliance with standards.

Perhaps the best way to accomplish this would be to support and build on the expertise of the existing Latin American standards organizations, the Dental Materiale Centre at Caracas Central University, and the Argentinean and Brazilian Institutes.

4. Laboratory

The United States and Canada have the most developed regulations in clinical laboratory practice, which includes reagents and in-vitro diagnostic kits. Some countries have limited legislation in respect to the registration or licensing of laboratories but few have legislation regarding the diagnostic reagents and equipment. Many countries do however have legislation relating to blood services (blood banks).

The Clinical Laboratory Improvement Act of 1988 (CLIA '88) is the most important legislation affecting the operation

of clinical laboratories. This law was in response to problems with the quality of tests performed by clinical laboratories, including physician office laboratories (POLs).

Laboratories performing simple laboratory procedures may be exempted from complying with standards and inspections by receiving a certificate of "waiver" (CLIA '88).

The Pan American Health Organization as Regional Office of the World Health Organization has continued promoting the development of standardization of laboratory methods and reagents at the national, regional, and international levels. We are in contact with National Committee for Clinical Laboratory Standards (NCCLS), International Standards Organization (ISO) and recently with the Latin American Confederation of Clinical Chemistry (COLABIOCLI) in pursuing common efforts to develop consensus on laboratory procedures and quality assessment programs. We have followed a multi pronged approach, that of consensus on standard procedures, reagent standardization, and quality assurance programs.

With regard to standard procedures, we have promoted the guidelines of the WHO Expert working groups and the NCCLS Standards. In respect to the reagents, we have reactivated the Latin American Regional Program of Diagnostic reagents, where we hope:

- a) to have an inventory of institutions and the diagnostic reagents produced in Latin America,
- b) to improve the component specifications of the reagents for exchange,
- c) to promote Good Manufacturing Practices (GMP) for reagents production,
- d) to improve the quality of the reagents by improving internal and production controls as well as efforts to scale up from the present bench-top production,
- e) to establish an institutional quality assurance program, and
- f) by providing a source of standardized reagents, we hope to stimulate a consensus on standardized procedures.

We promote the maintenance of internal quality controls, and establishment of national quality assessment schemes along the lines of the seven International External Quality Assessment Schemes (EQAS) (Clinical Chemistry, Hematology, Coagulation and Blood Groupings, Microbiology, Parasitology, HIV and VDRL).

There is a need to regulate monoclonal antibody and DNA Probe test kits. These may well be used by POLs and for self-monitoring by the public.

Last, but not least, is the need for regulation of the biosafety of laboratory workers.

5. Radiology

Suggestions for the regulation of radiological equipment.

1. Equipment registration

List equipment, its working condition and clinical application.

2. Epidemiology of Diseases

Use the epidemiological profile of diseases to develop plans for needed equipment.

3. Selection of Equipment

Criteria for equipment selection include effectiveness, safety, infrastructure, maintenance, and cost. To determine effectiveness, it is necessary to compare the technical specifications of the equipment and their impact in the clinical application for which the equipment is being selected.

- Effectiveness depends on specifications appropriate to clinical needs

- Safety implies the knowledge of mechanical, electrical, and radiological risks.
- Infrastructure considerations include available personnel, training, and present equipment technologies.

Diagnostic and therapeutic services to use the information produced by the equipment must be available.

Costs include: initial purchase, installation - including the shielding-, maintenance, spare parts, consumables, operator training, and the cost of final disposal.

4. Bidding process

Select equipment using a bidding process. Demand that the imported equipment complies with the regulations of the country of origin and any international standards.

5. Equipment purchase

The purchase contract should require acceptance testing with instruments and personnel provided by the manufacturer prior to final payment.

6. Acceptance testing

Includes:

Meeting manufacturer's technical specifications.

Meeting performance standards of the country of origin and international standards.

Compliance with the country's radiation protection laws and regulations.

7. Quality control program

Should be instituted by the user.

8. Regulation of governmental institutions

The government can revoke the licence when the institution is not able to document adequate quality control program.

9. Regulation of private institutions

Private institutions must submit documentation on medical and technical personnel which will operate it, acceptance testing results, and a quality control program which includes radiation dose measurements, before a licence is granted.

III. NATIONAL CONTEXT FOR THE REGULATION OF MEDICAL DEVICES

A. Canada's Health System

Health is a provincial responsibility. Physicians, nurses, and paramedics are licensed by the provinces, the hospitals and other medical facilities are also the responsibility of the provinces.

Each province has a medical plan which provides free medical care for its population, this includes hospital and outpatient care, physicians fees, and diagnostic and therapeutic services.

The federal government contributes a considerable proportion of the cost of these provincial plans on condition that the individual plans meet certain standards. These are:

- Public Administration

The plan must be publicly administrated and the organization open to scrutiny.

- Comprehensiveness

The plan must cover hospital, diagnostic, and therapeutic services and the professional fees of physicians, nurses, etc.

- Universality

The plan must be available to all residents.

- Portability

A patient must not lose his benefits when he moves from province to province.

- Coverage

Necessary Medical care out of the country must be paid for, up to its cost, in Canada.

- Accessibility

Adequate facilities must be provided to service the province's population.

B. Canada's Medical Devices Regulations

Control of medical devices in Canada is authorized by the Food and Drugs Act.

The Act:

- Prohibits the sale of unsafe devices.
- Prohibits false or misleading labelling or advertising.
- Provides for standards to be promulgated for particular devices or for particular characteristics.
- Provides authority to make regulations which will help to achieve the above.
- Provides for inspection and for seizure when required.

The Regulations

The main areas detailed in the regulations are:

- Adequate labelling must be provided explaining how to use the device in a safe and effective manner, what precautions should be taken, and what adverse effects may occur.
- A device offered for sale must have been adequately tested prior to sale and the tests must have shown the device to be safe and effective.
- Notification that the device is being sold or offered for sale must be made to the Bureau of Radiation and Medical

(BRMD).

- Evidence of safety of the device must be available in Canada.
- In the case of implanted devices, all the relevant information and test results to show the device to be safe and effective must be submitted to the BRMD. Only when this has been examined and been found to be adequate will sale be allowed.
- Standards which have been promulgated are printed in the Regulations as schedules.

IV. POLICY INSTRUMENTS FOR THE REGULATION OF MEDICAL DEVICES

These are the basic options available for the control of medical devices. The countries controlling medical devices use quite different mixes of these policy instruments to achieve their objective of ensuring that medical devices are safe and effective:

- A. Use of standard nomenclature.
- B. Data base containing:
 - Notifications
 - Certifications
 - Problem reports
 - Risk analyses
- C. Labelling requirements.
- D. Standards which devices must meet.

- E. Post-market surveillance of performance and problems with devices.
- F. Review of the test, safety, and performance data for devices of certain designated types (e.g. implants) that a manufacture wishes to sell.
- G. Inspections of manufacturing facilities to assess the quality of plant, equipment, process, and quality control.

A. Standard Nomenclature (SN)

The use of a standard nomenclature is fundamental to the efficient functioning of a medical device regulatory program

The nomenclature must be precisely defined and it must be detailed enough to differentiate between similar devices that need separate attention of any kind. The nomenclature must not be, on the other hand, cumbersome from sheer volume. These requirements point to the need of an hierarchical classification.

Use of SN means that different types of data (registration, problems, risk analyses, etc.) for a device can be readily correlated. It also means that data from different countries and organizations can be compared easily and without ambiguity; the SN clearly defines the device in question.

B. Data Base

All the activities of the program need to be recorded in a data base.

It is essential that all the information is either recorded in one data base or recorded in data bases which are compatible and can be linked. All information about a particular device should be available, and its presence indicated when any piece of information is retrieved.

The data base should use the standard nomenclature and it should contain at least:

- Notifications
- Certifications
- Problem reports
- Risk analyses
- Recalls

1. Notification

If control is to be exercised over the quality and safety of medical devices it is necessary to know what devices are available in the jurisdiction. Manufacturers can be made responsible for notifying the regulatory authority.

All devices available for sale in the country should be recorded (along with basic information about name, manufacturer, function, labels, etc.) and assigned a code which will always identify that precise device. It will also be given an appropriate standard nomenclature code.

Some countries require notification when sale has taken place but it is much more sensible that notification be required prior to sale. It would then be possible to prevent sale if the device was not considered suitable.

2. Certification

Certification is a requirement that the manufacturer must have notice from the regulatory authority that he has fulfilled same statutory requirements.

Any certification such as a permission to sell a device following pre-market approval should be recorded on the record of the device and in such a way that a list of certified devices can be retrieved when needed.

Users may find a list of certified devices useful in making purchase decisions.

Perhaps certified devices could be need carefully evaluated to determine whether the device should be de-certified.

3. Problem Reports

Problem reports are collected to monitor whether appropriate action is taken when a device malfunctions.

All reports of problems, recalls, retrofit, and cessation of sale should be entered on the devices record in such a way that lists of problem reports, recalls etc. can be retrieved as required.

Problem reports can be obtained from any source including manufacturers, hospitals, physicians, nurses, patients, etc.

Some countries have introduced compulsory reporting -- the results have not been entirely advantageous.

4. Risk Analysis

These are undertaken to evaluate groups of devices or particular characteristics of devices.

Any risks analyses that are undertaken or reported from acceptable sources should be entered in the data base for problem

reports.

They may consist of on-site investigation, laboratory testing, literature search, contract work, or any combination of these.

C. **Labelling**

Labelling includes markings on the actual device, labels attached to the device or its containers, instructions for use, and any explanatory material pertaining to the device.

The purchaser of a device needs to be given all necessary information about the proper way to use the device, precautions which need to be taken, and any adverse effects that might be expected. The labels are where this information should be found; adequate labelling needs to be insisted upon.

Any review of a device or risk assessment must include a thorough evaluation of the labelling.

D. **Standards**

There are several types of standards, those commonly used for devices include:

- Material Standards

Material standards help to characterise the new materials. Standards may define purity, strength, size, or any other characteristic which is important to the proper functioning of the final product.

- Fabrication standards

Fabrication standards define tolerances, temperatures, pressures speeds, or any other aspect of the manufacturing process that affects product quality.

- Inspection (Quality Control) standards

Inspection standards may specify how to select samples, how many samples to select, how to test samples, how to check environmental controls, etc.

- Safety standards

Safety standards define such things as bursting pressures, electrical insulation, failsafe mechanisms, etc.

- Performance standards

Performance standards may define speed of operation, electrical current produced, voltage attained, maximum pressure variation or any other characteristic on which the performance of the device depends.

- Disclosure standards

Disclosure standards define what characteristics of the device must be documented for the user. Disclosure standards may specify such things as label size and position.

Standards are useful where they can be put in effect without inhibiting new types of devices using new technologies. The last three types of standards listed - safety, performance and disclosure are safe in this respect but problems could be encountered with the first three types listed.

Standards are written by many organizations:

- Regulatory agencies
- Professional associations
- Trade associations
- National and international organization devoted solely to writing standards.

Standards from any of these bodies can be cited when useful.

Standards are only useful when they are adhered to. This requires supervision through certification that a particular product from a particular manufacturer meets the standard and through independent testing of samples on a regular basis to ensure compliance with the standard.

Writing standards is a lengthy and costly process, policing the writing of standards is also costly. Nevertheless, standards are useful and may be the preferred method of regulation in some instances.

E. Post-Market Surveillance

This is an important activity which can provide the information to improve devices and avoid problems with their use. Included in post-market surveillance are:

- Collecting reports of problems with devices from hospitals, physicians, nurses, medical technicians, manufacturers and patients. The information received can give an indication of trends in device problems, and generic problems with materials, device types, type of user, and environment.
- Problem investigation on site and in the laboratory can also be undertaken, both for specific problems and for generic problems.
- Risks analyses of particular types of device can be undertaken either because that type of device is seen to be giving problems or because potential for trouble is identified.
- Recalls of devices by manufacturers which includes physical recall, notification to users of change in operating procedures, new precautions, or any retrofit.

It is important to check the recall and to take any necessary action to ensure that it reaches all users.

All this information will be recorded in the data base.

F. Pre-Market Approval

This is a pro-active method of regulation. It involves the evaluation of specifications, performance characteristics, test results, quality control procedures and clinical trials information. Based on pre-market approval, a decision can be made as to whether the device should be allowed for open sale, allowed for investigational use, or not allowed for use at all.

The problems with pre-market approval are that it is expensive in time and manpower and it is difficult to know how much information is needed to decide whether the device is fit for use.

As a result of these problems its use has been effectively restricted to high risk devices. Many regulators believe that it should be abandoned because other methods of regulation are more cost effective.

G. Good Manufacturing Practice (G.M.P.) Inspections

This activity consists of inspecting manufacturing facilities. Trained inspectors are needed who can evaluate the various aspects of the manufacturing process.

Inspections may include assessment of the buildings, the environment, the machinery, cleanliness and sterility procedures, quality control, and any other aspect having an impact on the quality of the finished product.

Inspection is costly particularly of factories in foreign countries.

Cost can be reduced by being selective about what is inspected. Inter-governmental agreements allowing use of foreign inspection reports can also significantly cut cost and time.

G.M.P. are a useful tool in regulations but they do not assess the medical device produced ---- only the facility producing it.

V. PRESENT SITUATION OF REGULATION IN LATIN AMERICA AND THE CARIBBEAN

The main concerns were: the legal statutes for regulation, the relation of regulation and health care systems, health technology

information system, access and equity.

A. Legal Statutes

Although most of the countries appear to have a legal basis for regulation of medical devices, many participants emphasized the lack of adequate infrastructure, financial resources, and information systems to implement regulatory policies. In many instances, medical devices are being acquired without regard to safety, efficacy, manufacturing practices, international and national engineering standards, labelling, or recall information. A summary of the legal framework for the regulation of medical devices in Latin America and the Caribbean is presented on pages 37 - 42.

B. Regulation and Health Care Systems

The importance of co-operation between the medical device regulatory organization and the health care delivery system was emphasized with particular reference to long-term planning, device acquisition and the development of national manufacturing facilities.

The need for adequate facilities for services, calibration and user training was emphasized. National or sub-regional catalogues were seen as one means of standardizing the most useful equipment

and ensuring proper service and training.

Any safeguards introduced should apply equally to all equipment (including that donated or acquired through loans).

A need was seen for epidemiological studies and prospective analyses of technology to better select appropriate health technology.

C. Health Technology Information System

Countries have limited access to international information that would facilitate policy and decision making to improve planning, regulation, and management of medical devices (e.g. BRMD, CDRH and ECRI). Additionally, very little information was produced nationally to facilitate recalls of medical devices; inventories were deficient and it was difficult to standardize. The ECRI nomenclature and classification system was proposed for use in the region -- it could help to alleviate these problems.

D. Access and Equity

Equitable access to health technologies by all population groups was emphasized. Coverage for the medically indigent, is essential.

VI. FRAMEWORK FOR THE REGULATION OF MEDICAL DEVICES

A. Legal Framework

The legal framework for the regulation of medical devices in Latin America is broad and varies by country. However, it is possible to identify common features in all the countries studied: Argentina, Brazil, Colombia, Costa Rica, Cuba, Ecuador, Mexico, and Uruguay.

In general, legislation regulates medical devices under the same legal framework used to regulate pharmaceutical. There is also a tendency to regulate disposable equipment. However, in some cases, provisions are made to regulate more specialized and high cost technologies as well as technology transfers. A common element in the regulatory process is the consideration of risk factors, quality assurance, and safety standards.

As a common feature, regulations in the above mentioned countries have addressed the following aspects: definition of medical devices; regulatory agencies; fabrication standards; quality controls/clinical trials/technical evaluation for national and imported products; authorization for national and imported products; registration; inspection of manufacturing facilities, storage, and sale of medical devices; labelling requirements; qualified personnel to operate devices; licensing of manufactures,

storage, and sale of devices; exporting requirements, and policy considerations for the incorporation of expensive sophisticated devices.

1. **Definition.** Only a few countries have adopted a legal definition of medical devices, such as in Brazil "correlato", Ecuador "medical devices", Mexico "medical equipment", and Uruguay "therapeutic devices".

2. **Regulatory authority.** In most cases the regulatory authority is the Ministry of Health or one of its dependent agencies. In general, the regulatory agency is in charge of organizing, directing, and controlling manufacturing; registering, distributing, and commercializing of devices; licensing manufacture of the authorizing import and export; and to evaluating the need for incorporating medical devices to the health system.

3. **Fabrication standards.** Several laws establish fabrication standards for some medical devices in order to assure quality (Argentina), to safeguard the patient's health (Brazil, Costa Rica), or to comply with sanitary requirements (Cuba).

4. **Quality controls/clinical trials/technical evaluation.** Quality controls apply to both national and foreign devices, and require the certification by the country of origin (Argentina). The purpose of the control is to assure the technical quality of the

product (Brazil). There are also provisions for specific norms aimed at regulating the quality of services and controlling "risk factors" (Colombia). In some cases, the regulatory authority must guarantee that "articles for medical use" comply with the requirements established by legislation (Cuba). In others, the regulatory agency is required to perform a technical evaluation of expensive sophisticated devices, prior to its incorporation to the health system (Uruguay).

5. **Authorization.** Authorization is required for the production, importation and sale of products in the country. The authorization has limited duration, and should be periodically renewed (Argentina). In other cases, authorization is required for the import of technologies of high cost and complexity. The authorization should be granted in accordance to the national health policy and based primarily concepts of priority (Uruguay).

6. **Registration.** Only medical device and instruments, which the regulatory authority has determined whether or not to register, may be manufactured in the country. Registration is not necessary when the product is included in the lists produced by the regulatory authority. However, the devices, instruments, and accessories must be registered if they are subject to medical prescription, require special care, or are subject to other precautions during application to avoid damage to health (Brazil). Registration with the regulatory authority is also needed for importing,

manufacturing, transforming and selling of medical devices. Among these are disposable syringes, equipment for venoclysis, dialysis and transfusions (Colombia). The import or transfer of radioactive material and devices designed for diagnosis or medical therapy of scientific research, should be authorized and registered with the regulatory authority (Costa Rica). Registration with the regulatory authority is required for marketing, storage, or transport of medical devices. This requirement applies also to equipment destined to public institutions or when the equipment is donated. Registration is temporary and should be periodically renewed (Ecuador).

7. **Inspection and licensing of manufacturing facilities.** Establishments used to import, export, product, manufacture, market, and storage of disposable equipment should be licensed (Argentina, Brazil, Costa Rica, Cuba). However, the regulatory agency may authorize, for limited periods of time, the manufacture of products to assure the quality and characteristics of the products (Argentina). Finally, the sale of medical devices could take place only in establishments determined by law (Uruguay).

8. **Labelling.** Labelling is required for exportat of products. In this case, it is necessary to consider the language of the country of destination (Argentina). Labelling in Spanish, including the type of the device and instructions for use is required for

national products. For imported products. Labelling in Spanish is required (Mexico).

9. **Qualified personnel requirements.** Medical devices that could harm a patient, should be operated and managed by qualified personnel only (Costa Rica).

10. **Exportations.** Products for export should observe the same manufacture, packing, and identification requirements as those for national consumption (Argentina).

11. **Importation.** Imported medical devices require authorization and licensing to assure their quality (Argentina). In other cases, import of medical devices, without the authorization of the regulatory agency is forbidden. There is also the need to submit to the regulatory authority information on the nature of the product, recommendations for use, security considerations and period of guarantee (Brazil). A similar principle applies when, due to poor quality or defects, medical devices do not comply with the established requirements for the purpose they were designed for, or if they entail a risk for health (Costa Rica). Permit is also required for importing samples and raw material for the health registry (Ecuador). Finally, the quality of the imported technology should be nationally and internationally recognized. Authorization for import is not granted to equipment in the experimental phase (Uruguay).

12. **Maintenance requirements.** The regulatory authority should enact regulations to ensure proper intallation, maintenance, and calibration of medical devices (Cuba). Maintenance requirements should also ensure the continuity of production of the equipment for the period of its productive life or longer, the provision of operation and service manuals, the presence in the country of a technical unit capable of servicing the device, and training of specialized personnel (Uruguay).

13. **Policy considerations for the incorporation of high cost and sophistication devices.** Considerations are made for the enactment of a national policy aimed at regulating the incorporation of medical devices of high cost and sophistication, on the bases of priority needs and economic feasibility, and in compliance with the health policy established by the regulatory authority (Uruguay).

LEGAL INDEX

ARGENTINA

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BRAZIL

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COSTA RICA

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ECUADOR

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MEXICO

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URUGUAY

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B. Operational Framework

Dr. Letourneau gave a summary of medical device options. The two main requirements:

- to assess safety and effectiveness of devices
- to determine which is the best available device for the money

are unrelated determinations. Any attempt to mix the two will result in failure of both.

An Ideal Control Program would comprise:

1. A system of notification by the manufacturer or importer of a device prior to sale, at their expense.
2. Pre-Market approval of all devices.
each device would be assigned to a risk class. The depth of evaluation would depend on its potential for causing harm.
3. Post-Market Surveillance to determine how the device performs in actual service.
Compulsory reporting of problems and malfunctions by manufacturers and users.
4. Full investigation of all problems with the results feeding back to notification, pre-market appraisal, and to the individual or agency reporting the problem.
5. A band of well trained inspectors to inspect all manufacturing facilities for Good Manufacturing

Practices.

6. A group of expert scientists with comprehensive laboratory facilities to test devices for compliance with standards and to investigate the problems.

This is not a feasible option for any country because of the large amount of money and manpower required.

Even the U.S.A. Food and Drug Administration with 1, 100 professionals to run their program are constantly criticized for not doing a good job.

Any regulatory approach which relies heavily on pre-market approval is bound to fail. Medical device manufacturers spend about 2 billion dollars per year on research. Regulatory agencies cannot match this, so they cannot possibly thoroughly check the manufacturer's work. Other mechanisms must be found.

A feasible system at reasonable cost

The programs which could be introduced without great cost are listed in order of importance. Using simple computers to organize all the data would enable the programs to be run with minimal manpower. Each additional program would of course increase the cost and each country would need to decide how far to go with its own program.

The fundamental principal is to make the manufacturers and importers do the work and also make them pay for it.

1. Notification of all devices sold in the country to an office established for device regulation.
2. Certification by the manufacturer that his device complies with some appropriate and acceptable standard.
3. Declaration of:
 - 3.1 Acceptance of the device by any other country;
 - 3.2 Recall of the device in any other country;
 - 3.3 Present availability of the device in any other country.
4. Post-Market Surveillance of any problems with devices by manufacturers and users. This would result in a body of experience data with devices which needs to be made available to the users in order to encourage their cooperation.

70% of problems are users related because:

- the device is defective because of local environmental condition (heat-humidity, etc.)

- the device is perfect but incorrectly used because of inadequate instructions for the user.
- the device is perfect but fails because it is not used properly (poor training).
- the device is perfect but fails because of inadequate maintenance.

With more money one could:

5. Assemble a small group of specialist scientist to do research on specific problems which manufacturers are not prepared to tackle. These are often generic problems.
6. Have inspectors to perform Good Manufacturing Practice inspections of home industries and to evaluate other countries inspection reports.
7. Arrange access to medical device data banks world-wide to assist in all these programs.

VII. RECOMMENDATIONS FOR THE REGULATION OF MEDICAL DEVICES IN LATIN AMERICA AND THE CARIBBEAN

A. Basic Principles

1. The Health needs, based on the socio-economic situation of the country, must determine the program to be set up.
2. The government must ensure that health facilities are equally available to the whole population.
3. A Bureau or Office for Medical Device Control (however small) should be established as a focal point for any program initiated.
4. The types of devices to be regulated will be determined by reference to the morbidity/mortality profile of the country.
5. Safety is not absolute and should be assessed with reference to the risk/benefit ratio.
6. Effectiveness of each device must be ensured.
7. More information exchange between all countries should be encouraged including regular seminars on the subject.

8. In respect to nomenclature the possibility was explored to adopt ECRI's nomenclature and classification system.

B. Action Program

1. Registration of importers, manufacturers, and donors is a fundamental requirement. It is suggested that manufacturers, importers, and distributors be charged a registration fee to cover the cost of the program.
2. Registered device suppliers should be required to:
 - a) Provide an acceptable risk/benefit assessment of any device to be supplied.
 - b) Provide evidence of the effectiveness of the device.
 - c) Provide training for operators of the device.
 - d) Ensure availability of consumables, spares, and services for the device.

3. The requirements in 2/a and may be met by
 - a) A certificate of acceptance of the device from the country of origin.
 - b) A pre-market approval by another acceptable regulatory authority.
 - c) Certification by an acceptable outside agency.
 - d) Pre-market approval by the receiving country or by its consultants.
4. An initial survey of devices in each type of health facility should be completed with safety and effectiveness assessments.
5. A post-market surveillance program should be initiated including:
 - Problem reports from users and suppliers.
 - Surveys of selected types of devices.
6. An inter-country data bank should be established including:
 - Registration information

- Post-Market Surveillance information
- Purchasing information
- Educational material

7. Radiation emitting devices will follow the suggestions presented by Dr. Cari Borrás and Ing. Jorge Skvarca (presented on pages).

C. Future Activities

1. Registry of all medical devices. For diagnostic imaging, radiotherapy and nuclear medicine equipment, follow UNSCEAR suggestions.
2. Subgroup to homologate nomenclature, classification and registration.
3. Meeting in 1991 to monitor and evaluate progress.

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Sagripanti, Jose-Luis	La Ciencia Experimental en la Regulación de Dispositivos Médicos. Center for Devices and Radiological Health, Food and Drug Administration, Rockville, Md.
Weber, Frances	Post Market Surveillance System. Bureau of Radiation and Medical Device, National Health and Welfare, Ottawa, Canada.
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Health Services Development Program (Laboratory, Radiology, Dentistry,
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ADVISORY GROUP
9-10 May 1990

S E M I N A R
2-8 May 1990

WASHINGTON, D.C.
7 - 10 May 1990

OTTAWA, CANADA
2 - 4 MAY 1990

U S A Experience 8 May

ence

3 MAY

2 May

9:00 AM 8:45 AM

Inauguration
E. Lévesque,
G. Coe & R. Dresser

Visit to ERMD,
Radiation
Emitting
Devices
D. Grogan

**The USA Health
System
J. Harrell**

Device
Nomenclature
Info. System &
Risk Analysis
C. Reynolds
J. Nobel

Formulation
of
Proposal
(cont.)

CONFEE

Agenda of the
Meeting - G. Coe
Constitutional Aspects
of Reg. Policies -
R. Dresser
Reg. of Med. Devices,
Europe - L. Faro
Reg. of Med. Devices,
Spain - M.C. Abad Luna

Post-market
Surveillance

Overview
The USA
Regulatory
System y

M. Castillo
W. Gurdaker

Laboratory
and
Regulation

Formulation of
Proposal
(cont.)

12:30 pm

LUNCH

Working Group:
Medical
Device
Regulatory
Problems

**Pre-Market
Review**

**General Controls:
Registration
Listing, Labeling &
Good Manufacturing
Practices**

Post-Market
Surveillance

C. Reynolds

Presentation of Proposal

3:30 PM

CONFEE

**Regulatory Concerns
in specialized health
service fields:**
A. Viladegut
V. Escutia
E. Fefer
C. Borrás

Research and Standards (Home Use Devices)

Pre-Market Approval Notification	H N4m
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Standards
P. White
E. March

Closing Remarks

6:00 Reception -
Natl. Gallery
7:00 Dinner -

5:30-6:30 ECRI
J. Nobel