

GOBIERNO DE CHILE
INSTITUTO DE SALUD PÚBLICA

MEDICAL DEVICES REGULATIONS CHILE

**MINISTRY OF HEALTH
PUBLIC HEALTH INSTITUTE OF CHILE (ISP)**

National Control Department

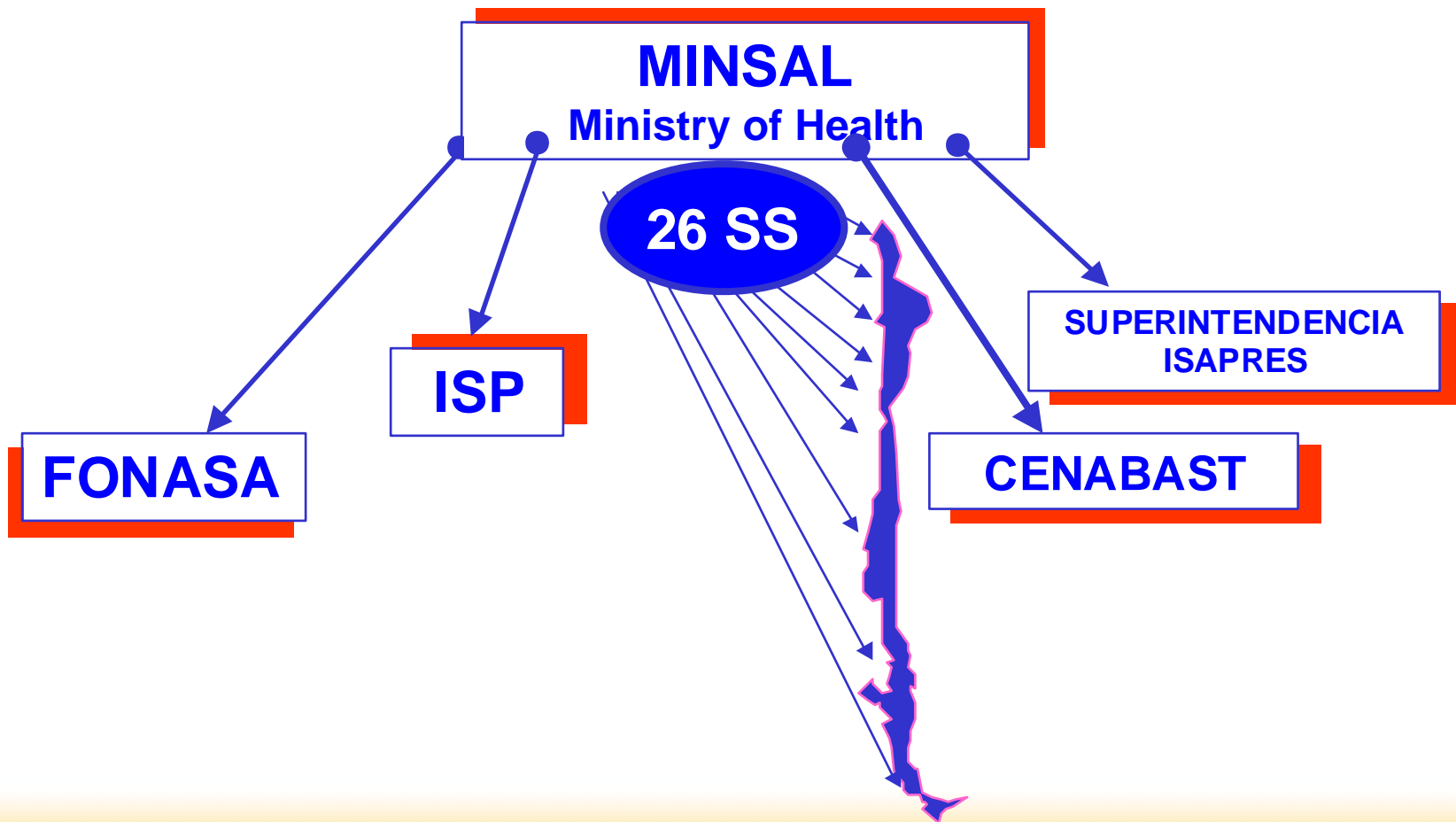
Medical Devices Subdepartment

Dra. BQ. Nancy Fernández Nilo

9th GHTF CONFERENCE, 12-16 May 2002 , SINGAPORE



GOBIERNO DE CHILE
MINISTERIO DE SALUD





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**HEALTH
REGULATIONS**

INSTITUTO DE SALUD PÚBLICA DE CHILE



MANAGEMENT

FINANCE, ADMINISTRATION,
INTERNAL SERVICES
DEPARTMENT

HEALTH LABORATORIES
DEPARTMENT

NATIONAL
CONTROL DEPARTMENT

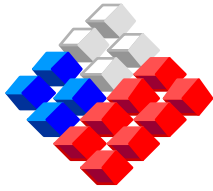
OCCUPATIONAL HEALTH
ENVIRONMENTAL CONTROL
DEPARTMENT

PRODUCTION
DEPARTMENT

PHARMACEUTICAL, COSMETICS,
MEDICAL FOOD

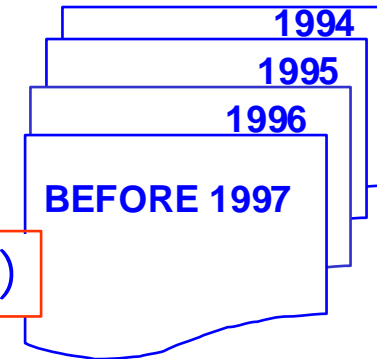
HEALTH CODE
D.S. 1876/1995

MEDICAL DEVICES (MD)

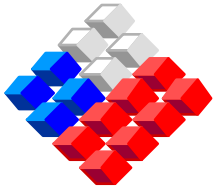


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MEDICAL DEVICES (M.D.)



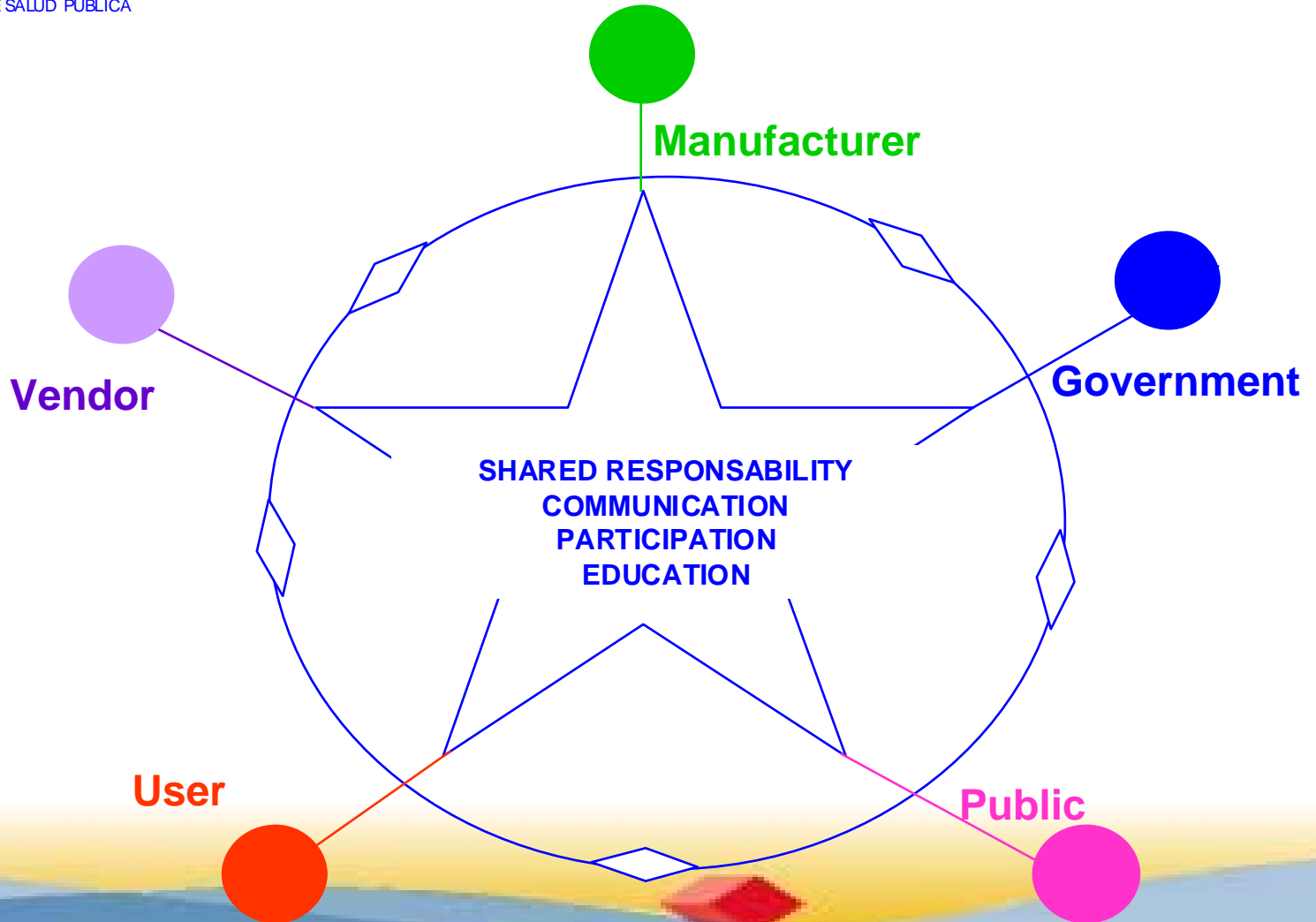
- Lack of legislation that regulates these products.
- Deficit of information regarding production process.
- Lack of national regulations with quality especifications and characteristics.
- Impact caused by defective products was unknwon.

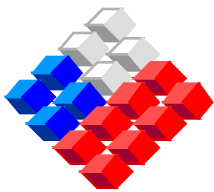


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SHARED RESPONSIBILITY FOR MEDICAL DEVICE SAFETY AND EFFECTIVENESS

A Guideline for the Development of Medical Devices Regulations. April 1999. PAHO

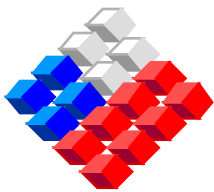




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Medical Devices Regulatory Framework Law No. 19,497

The natural or juridical person who manufactures, imports, commercialises or distributes medical devices will have to undertake quality control and certification of these products in institutions or laboratories approved and monitored by the Public Health Institute.



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EXPECTED BENEFITS

- **An increase of the Government regulatory role over products used to provide health services to the population.**
- **To ensure the safety, performance and quality of medical devices.**
- **A decrease of resources inappropriately spent by the Government and private companies on unreliable health services.**

Medical Devices Regulations

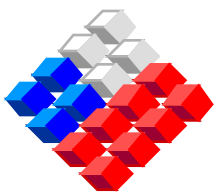
**MEDICAL DEVICES
RULING
CONSULTED TO:**

- **Manufacturers and distributors (60 COMPANIES)**
- **Scientific societies**
- **National Institute of Normalisation (INN)**
- **Experts in quality systems**
- **Certification of quality system organisations**
- **Health professionals: laboratory clinics (ALACLIN), hospitals, pharmacies, etc.)**

RULING N° 825

Ruling No. 825 was issued in August 1999, which activates the law and will be gradually implemented.

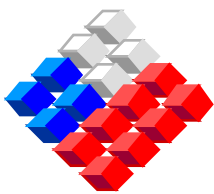
This ruling is based on the USA, Canada and EU regulations, adapted to the social and health situation in Chile and considering that more than 90 % of the commercialised medical devices are imported.



Medical Devices Regulations

This ruling basic structure considers the following main elements:

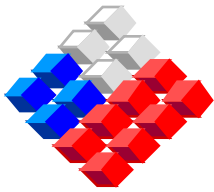
- 1** Identification of the manufacturer, distributor and product before its commercialisation.
- 2** To demand manufacturers or distributors to count on quality systems in their production processes.
- 3** Classification of products according to ascendent risk level (Class I, II, III, IV).
- 4** Products conformity assessment, based on national or international regulations, which will be conducted by an independent company or organisation.
- 5** Monitoring during the commercialisation process.



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CLASSIFICATION OF MEDICAL DEVICES ACCORDING TO THE RISK LEVEL LINKED TO THEIR USE

- Class I:** Including devices that show a low risk level.
- Class II:** Including devices that show a moderate risk level.
- Class III:** Including devices that show a high potential of risk.
- Class IV:** Including the most critical devices regarding risk.



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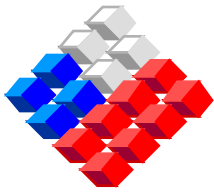
REGULATORY CONTROL REQUIRED ACCORDING TO CLASSIFICATION

CLASS I

- **Manufacturer identification.**
- **Product identification: internal and external printing (packing and manual of instructions), lot number, raw material listing and functioning description.**
- **Chemical and biological assays, sterilisation and control certification.**
- **Storage conditions and expiry date.**
- **National or international product quality control certification.**
- **Export certification issued by the country the origin.**
- **Performance assessment with international standards (harmonisation).**

CLASS II

- **All requirements included in Class I.**
- **Certification of quality system ISO-9002 or GMP.**



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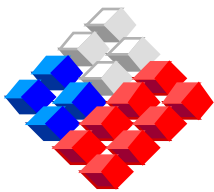
REGULATORY CONTROL REQUIRED ACCORDING TO CLASSIFICATION

CLASS III

- All the requirements included in Class II.
- Scientific literature.
- Studies undertaken by the manufacturer that prove product effectiveness and security.
- Certification of quality system: ISO-9002 or ISO 9001 or GMP.

CLASS IV

- All the requirements included in Class III.
- Studies with numbers of patients statistically significant on various areas: biological, safety, etc.
- Studies on risks inherent to the use of devices.

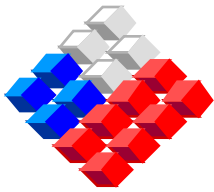


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PROPOSAL FOR FIRST DECREE ACCORDING TO ARTICLE No.22 OF THE MEDICAL DEVICES RULING

The first five products that are included in the first decree:

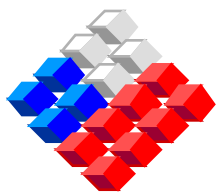
- 1) surgical gloves
- 2) examination gloves
- 3) condoms
- 4) needles
- 5) syringes.



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INSTITUTIONS INVOLVED

- The Public Health Institute of Chile.
- The National Institute of Normalisation.
- Accredited Certification Organism.
- Health Services.

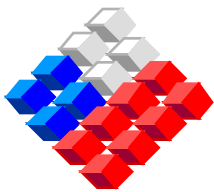


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POST-MARKET SURVEILLANCE SYSTEM

To enhance health protection for patients as well as users decreasing so the possibility of accident occurrence through a surveillance network:

- With the public and private health services, manufacturers and users.
- A team work to standardised information schedule depending on the incident level of seriousness.
- An on-going educational process.



POSSIBLE PROBLEMS WITH MEDICAL DEVICES

- **Malfunctioning:** mechanical or software of the medical devices, manufacturing default due to design and problems with the used materials.
- **Problems with use:** incomplete printing of the packing or manual of instructions, confusing indications, design problems that make it difficult for staff to use.
- **Clinical problems:** patients who show a previous deteriorated condition, allergic people to the medical devices, using contaminated products that cause severe infections, etc.

WHEN TO INFORM?

- **Death.**
- **Health serious deterioration.**
- **Malfunctioning of one medical device that may cause health deterioration.**
- **Incorrect or lack of indications on the packing and/or instructions of use.**

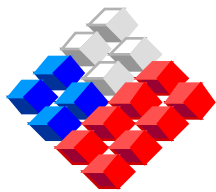


WHO INFORMS IN A POST-MARKET SURVEILLANCE SYSTEM?

- Health professionals and staff, manufacturers or users who notice or come to know about incidents or risks related to malfunctioning, manufacturing defaults or adverse reactions to the medical devices, before, during and after being used by a health service.

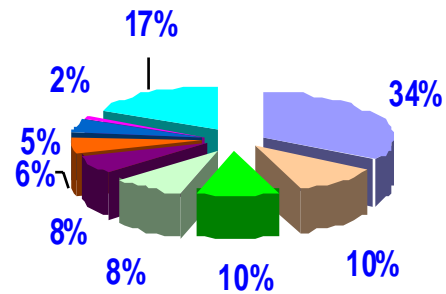
WHAT IS THE HEALTH AUTHORITIES ROLE?

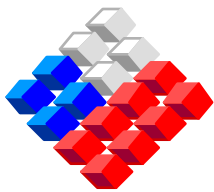
- To record and evaluate notifications informed by professionals, manufacturers and users.
- An on-going educational training of the participants involved.
- To implement corrective actions to prevent new events from occurring.
- To request manufacturers and/or distributors to undertake clinical studies when necessary.



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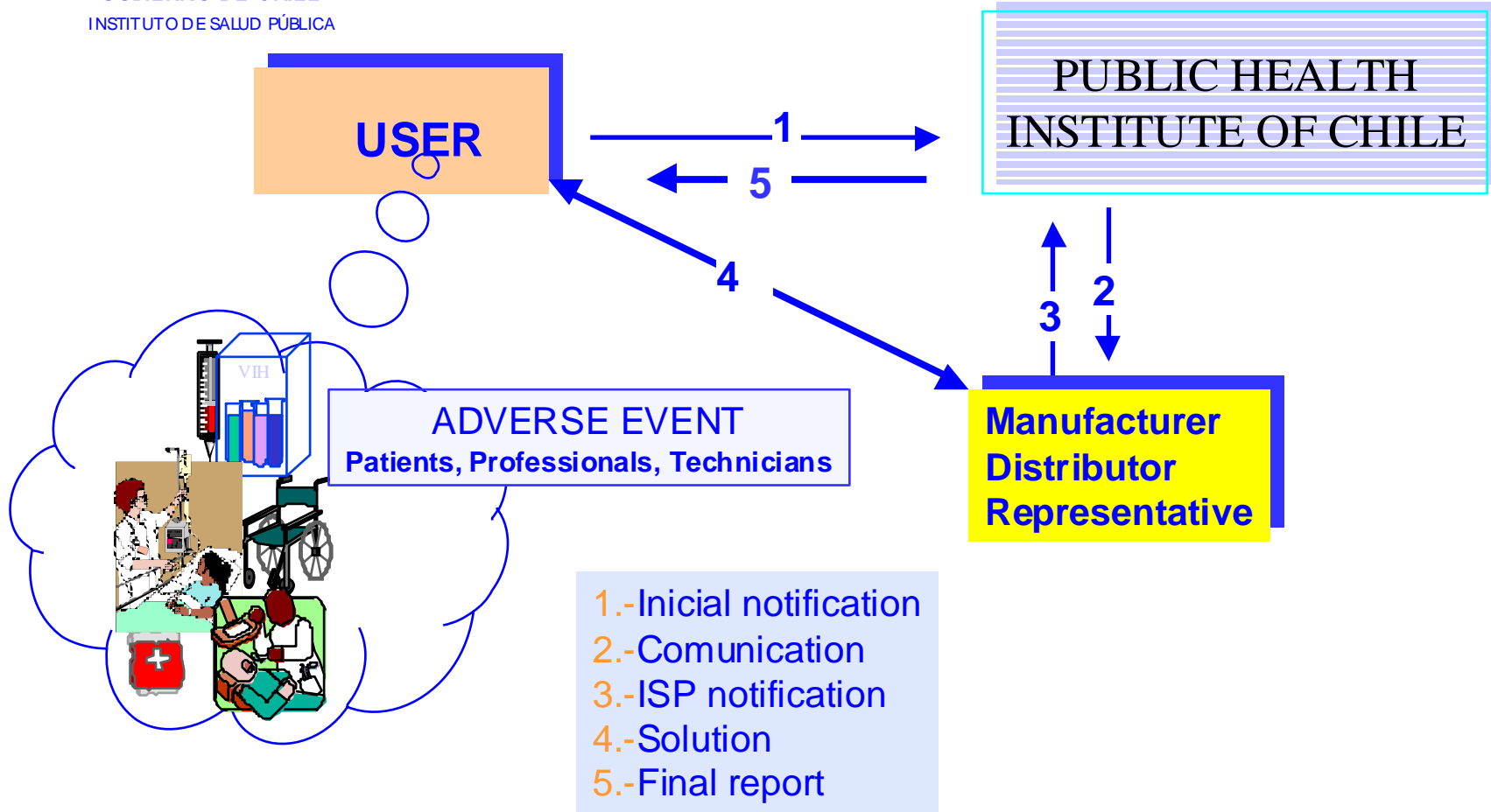
Distribution by device in percentage terms (1998-2002) n=106





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POST-MARKET SURVEILLANCE SYSTEM

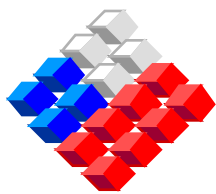


5 Years of activities aiming at Establishing a regulatory framework

- ***Creation and incorporation of medical device regulations into the Health Code: law and rules.***
- ***Homologation of ISO and Chilean Norms for medical devices according to the existing regulations.***
- ***Creation of an assay laboratory to verify medical devices conformity.***
- ***Promotion and backing for the creation of applied certification organisms.***
- ***Implementation of a post-market surveillance system for medical devices.***
- ***Dissemination of information to educate health professionals, manufacturers and/or distributors and users through seminars, talks and writing material.***
- ***Including Chile in the International Organisms activities in the area (OPS, GHTF).***

The aforementioned activities, have been undertaken with the constant participation of all stakeholders.

WE WISH THAT 2002 WILL BE THE YEAR WHEN OUR MODEL CONSOLIDATES.



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THANK YOU
VERY MUCH

