



**WEBINAR TRANSCRIPTION:**

**REGULATING MEDICAL DEVICES:  
WHAT, HOW, WHY, AND WHEN?  
LESSONS LEARNED FROM CHILE.**

*Presented by Josée Hansen. June 20, 2019*

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# **REGULATING MEDICAL DEVICES: WHAT, HOW, WHY, AND WHEN? LESSONS LEARNED FROM CHILE.**

**June 20, 2019**

Presented by **Josée Hansen**

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# REGULATING MEDICAL DEVICES: WHAT, WHY, HOW AND WHEN? LESSONS LEARNED FROM CHILE.

Josée HANSEN  
Consultor Red CRITERIA del BID  
20 Junio 2019



## IADB Project

Proyecto de apoyo al fortalecimiento de la regulación de dispositivos médicos en Chile

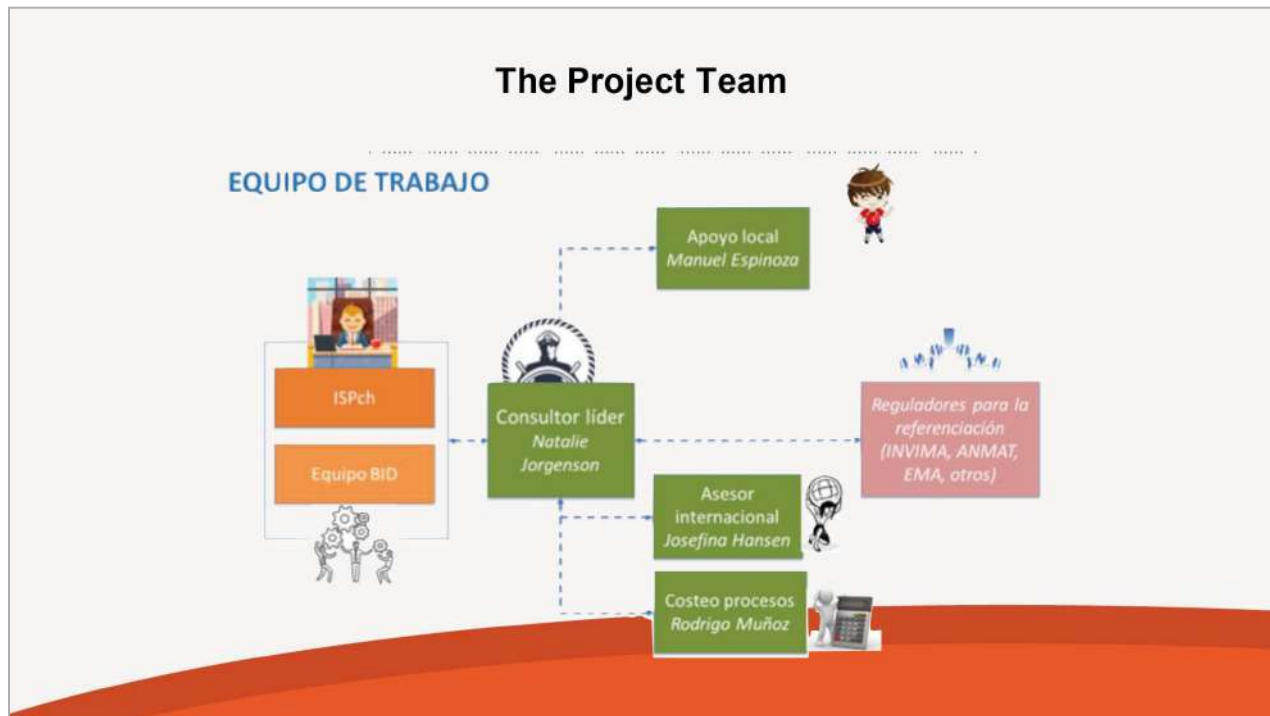
### FASES



# IADB PROJECT

**Minute 00:04:47**

Let me first say that I will talk about regulating medical devices and I will touch upon a series of topics. But before that I would like to introduce this project of the Inter-American Development Bank, or BID (Banco Interamericano de Desarrollo) in Spanish. The Inter-American Development Bank supports Chile in strengthening the medical device regulation. There are two phases. The first phase has ended in January this year and was about the gap analysis of the Chilean regulatory system for medical devices. And currently the master plan of implementation is being developed. So there will be a master plan for the implementation of medical devices in Chile.



## THE PROJECT TEAM

**Minute 00:05:34**

This is the team. BID is very closely collaborating with the regulatory authorities in Chile, which is the ISP (Instituto de Salud Pública). And there is a consultant, Natalie Jorgenson. She is from Argentina. There are two national consultants and I am the international consultant in this team.

## Contents

- What are medical devices?
- Why do we need to regulate medical devices?
- Principles of medical devices regulation
- Stepwise approach
- Good regulatory practices
- International harmonization
- When is the appropriate moment to start regulating?
- Patient medical devices, safe patient care
- Lessons from Chile

## CONTENTS

### Minute 00:05:55

I will guide you through the presentation by touching upon the following topics. What are medical devices? Why do we need to regulate medical devices? And how are we going to effectively and efficiently regulate medical devices? Then we will look at when to start regulating medical devices. I will also talk briefly about patient safety and some serious adverse events happening with medical devices worldwide. And I will end the presentation with some slides regarding lessons learned from Chile.

## **WHA Resolution 67.20**

### **Regulatory system strengthening for medical products**

Recognizing that **effective regulatory systems are an essential component of health system strengthening and contribute to better public health outcomes**, that regulators are an essential part of the health workforce, and that inefficient regulatory systems themselves can be a barrier to access to safe, effective and quality medical products;

[http://apps.who.int/gb/ebwha/pdf\\_files/WHA67/A67\\_R20-en.pdf](http://apps.who.int/gb/ebwha/pdf_files/WHA67/A67_R20-en.pdf)

## **WHA RESOLUTION 67.20**

### **Minute 00:06:35**

This is an important resolution. In 2014 the World Health Assembly, which is the Annual Meeting of the member states of the World Health Organization, adopted a resolution, which relates regulating medical devices, medicines and vaccines to public health. And that is important. It says that effective regulatory systems are an essential component of health system strengthening and contribute to better public health outcomes.

## WHA Resolution 67.20 Medical devices

... to prioritize support for establishing and strengthening regional and subregional networks of regulatory authorities, as appropriate, including strengthening areas of regulation of health products **that are the least developed, such as regulation of medical devices, including diagnostics;**

[http://apps.who.int/gb/ebwaha/pdf\\_files/WHA67/A67\\_R20-en.pdf](http://apps.who.int/gb/ebwaha/pdf_files/WHA67/A67_R20-en.pdf)

## WHA RESOLUTION 67.20

### Minute 00:07:06

The resolution also specifically addresses medical devices as one of the high priority areas and it encourages member states to collaborate in strengthening their regulation.



## Medical devices: a myriad of products



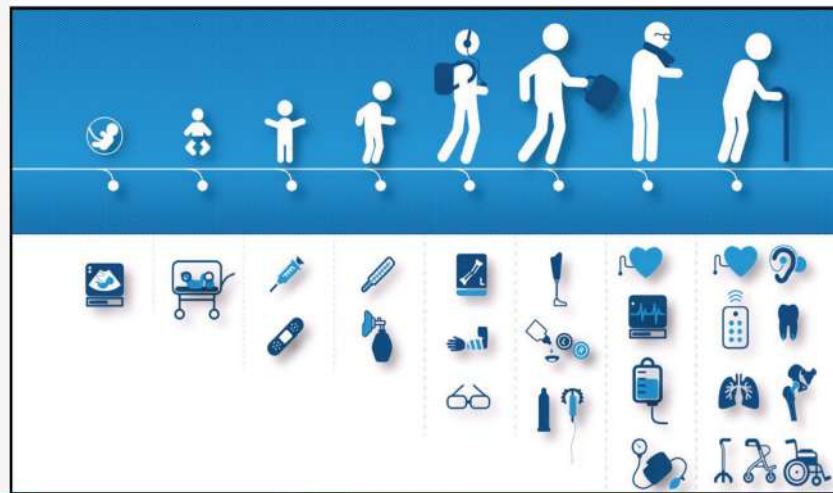
- Estimated 2 million different kinds on the global market
- Commercial life cycle estimated 18-24 months
- A global market
- A crucial component of health care

## MEDICAL DEVICES: A MYRIAD OF PRODUCTS

### Minute 00:07:24

So what are we talking about? What are medical devices? Well it is a huge group of products of very different kinds, from a wheel chair, even a walking stick to a hip implant, a diagnostic device, surgical gloves, contraceptives, surgical equipment, CT scans, MRI scan equipment, you name it. There are an estimated 2 million different medical devices on the market worldwide. Unlike medicines they have a commercial life cycle of approximately one and a half to two years, which is very short. And there is a global market. If you look at the global picture there are, in fact, three countries, which are leading the global market in terms of sales. They are the US, the EU and Japan. So most countries in the world are importing countries and that has an impact. I will come back to that later. Currently, the lower-technology medical devices are more and more produced in countries like China, India, Brazil, Mexico, Korea and Taiwan. Medical devices are a crucial component of healthcare. You could say that there is no medical intervention, unless you talk about speaking to a patient, that does not involve a medical device.

## Use of medical devices during life



## USE OF MEDICAL DEVICES DURING LIFE

### Minute 00:08:58

This is a picture of the phases of a human life, from before birth until very old. Medical devices are being used in every phase of a person's life. Before birth in monitoring pregnancy and until the last phase of life where a person needs a walking stick a hip implement, a hearing aid, dental implants and so forth.

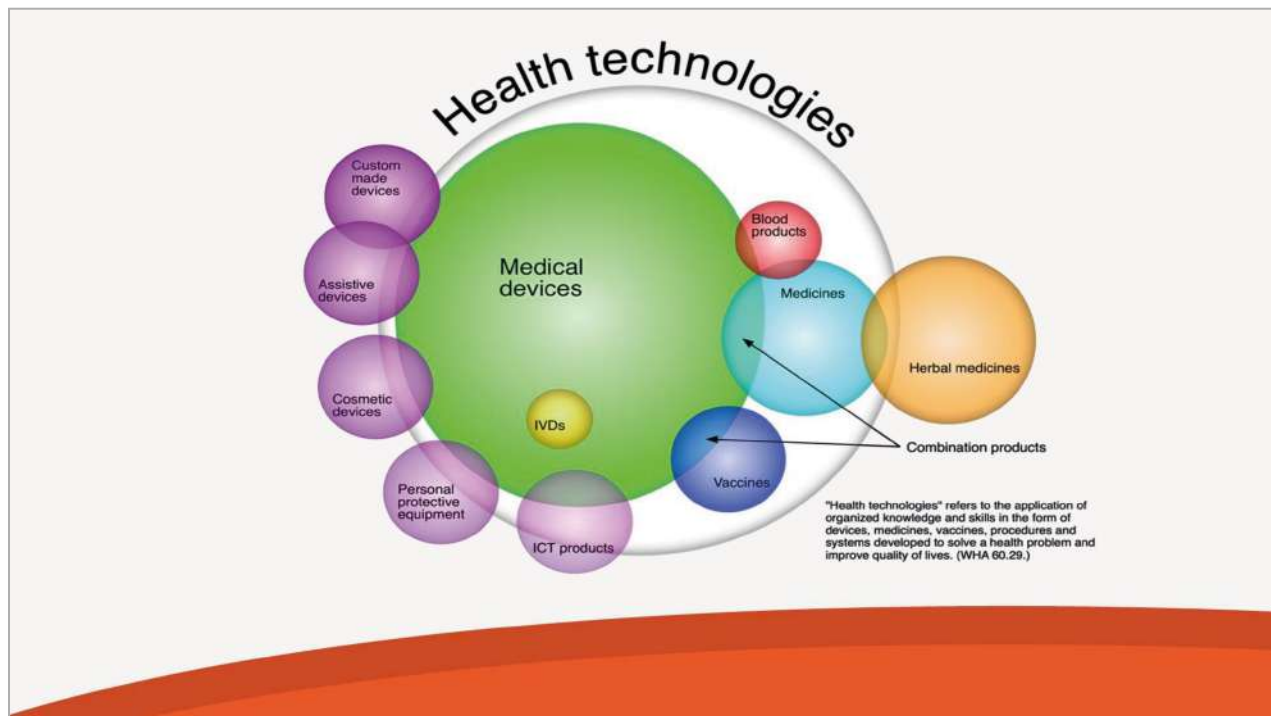
# Definitions

| medicinal product   | medical device   |
|---|--|
| <p>Any substance or mixture of substances that is manufactured for sale or distribution, sold, supplied, offered for sale or presented for use in:</p> <p>(i) <b>the treatment, mitigation, cure, prevention or diagnosis of disease</b>, an abnormal physical state or the symptoms thereof and abnormal physiological conditions in human or animal; or</p> <p>(ii) the restoration, correction or modification of organic functions in human or animal.</p> <p><a href="http://www.who.int/medicines/services/expertcommittees/pharmprep/20111208_QASterminologyDB.pdf?ua=1">http://www.who.int/medicines/services/expertcommittees/pharmprep/20111208_QASterminologyDB.pdf?ua=1</a></p> | <p>... instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical <b>purpose(s)</b> of:</p> <ul style="list-style-type: none"> <li>-<b>diagnosis, prevention, monitoring, treatment or alleviation of disease</b>,</li> <li>-diagnosis, monitoring, treatment, alleviation of or compensation for an injury,</li> <li>-investigation, replacement, modification, or support of the anatomy or of a physiological process,</li> <li>-supporting or sustaining life,</li> <li>-control of conception,</li> <li>-disinfection of medical devices,</li> <li>-providing information by means of in vitro examination of specimens derived from the human body;</li> <li>-and <b>does NOT</b> achieve its primary intended action by <b>pharmacological, immunological or metabolic means</b>.</li> </ul> <p><a href="http://www.imdrf.org/docs/ghf/final/sg1/technical-docs/ghf-sg1-n071-2012-definition-of-terms-120516.pdf">http://www.imdrf.org/docs/ghf/final/sg1/technical-docs/ghf-sg1-n071-2012-definition-of-terms-120516.pdf</a></p> |

## DEFINITIONS

### Minute 00:09:24

Medicines are a product group which most people are familiar with. They are different from medical devices but there are also some commonalities. Let me start with the definition. I highlighted the commonalities in green. If you look at the definition you will see that both medical devices and medicines are used in the diagnosis, prevention and treatment of disease. The difference is their mode of action, highlighted in red. A medical device does not achieve its primary intended action by pharmacological, immunological or metabolic means. This seems straightforward, but it does create problems.



## HEALTH TECHNOLOGIES

### Minute 00:10:10

I want to show you this one. This is a diagram of all kind of medical products. And there are borderlines between medicines and medical devices. I will mention a few of them. For example, a dialyzing solution, is it a medicine or a medical device? Its primary action is a physical one not metabolic, not immunological, and not pharmacological. Strictly speaking it would be a medical device, however in many countries dialyzing solutions are still registered as medicines. Another example is alcohol. Is it a medical device, or is it medicine? If it is used to disinfect the skin it can be considered a medicine but if it is used to disinfect another medical device, it is considered a medical device.

On the other side of the spectrum there are the cosmetics. Is a cosmetic implant a medical device? It doesn't have any medical purposes. How to treat them? In some countries they are considered only a cosmetic and in other countries they are considered a medical device. Another group are the ICT products. Is software a medical device? And what do you think about the latest version of the Apple Watch, which monitors the heart function? Is it a medical device? All in all those borderline products are real challenges for many regulators.

## Commonalities and differences

|                     | Medicines              | Medical devices (+IVDs)                              |
|---------------------|------------------------|--|
| Diversity           | Approx. 40 NCE's /year | >>> 100,000; average commercial life cycle 18 months |
| Innovation          | 'Revolution'           | Incremental improvement                              |
| Durability          | Single use             | Single use, multiple use, permanent                  |
| Responsibilities    | Physician; pharmacist  | Usually not assigned                                 |
| Context for use     | Independent            | Highly dependant                                     |
| Clinical guidelines | Detailed prescribed    | Not mentioned  |

## COMMONALITIES AND DIFFERENCES

### Minute 00:11:51

I will talk about some more differences between medicines and medical devices. As far as medicines are concerned, there are only 40 to 50 new medicines introduced per year on the market worldwide. That it's really not a lot. If you look, for instance, at FDA they approved 40 new medicines last year on the market. Regarding medical devices there are many more, especially because they have such a short commercial lifecycle.

Another topic, which I just would like to mention are the clinical guidelines. Just take any clinical guideline and look for the medical devices linked to the diagnosis of treatment. There are no or very limited mentions in the clinical guidelines. For medicines, on the other hand, clinical guidelines usually contain to a high level of detailed instructions of which medicines to use and in which doses. The lack of medical devices in clinical guidelines has as a consequence that a health care professional doesn't know which medical device to use.

## Commonalities and differences

|                         | Medicines  | Medical devices (+IVDs)   |
|-------------------------|--|---|
| Benefit/risk assessment | Each individual product                            | Risk classes. Premarket assessment of high risk medical devices |
| Nomenclature            | International Non Proprietary Name                 | GMDN<br>UMDNS<br>ISO 9999<br>UNSPSC<br>Others                   |
| Industry composition    | Dominated by large multinationals; Small # of SMEs | Over 80% SMEs;<br>20 companies dominate sales revenue           |
| Sales global            | 900 billion US\$                                   | > 500 billion US\$  |

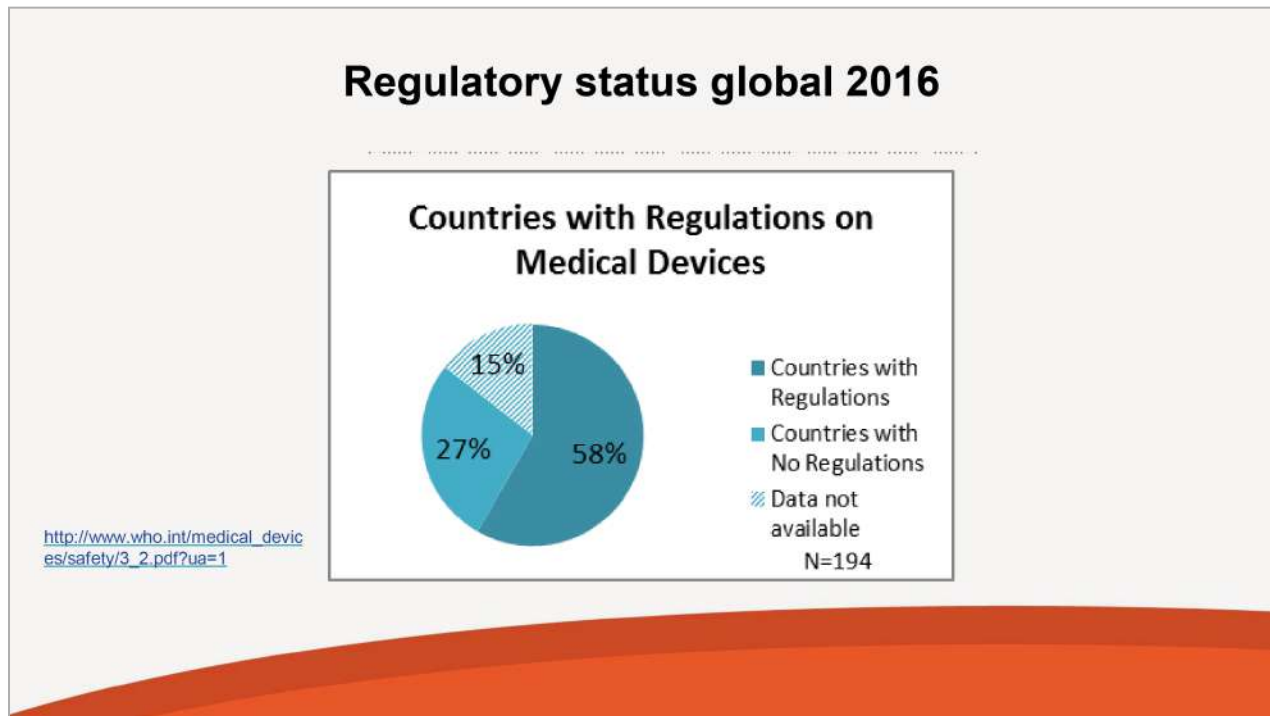
## COMMONALITIES AND DIFFERENCES

### Minute 00:13:15

As you perhaps know, each individual medicine is assessed for their benefits, risks and their quality. This assessment is being performed by a regulatory authority. Considering the number of medical devices that is just not possible. If you would apply a medicine system to medical devices, and there are people who are promoting that, it would have as an effect that only a very few number of medical devices would become available for the patient. So as a way forward it was chosen by regulators worldwide to use the concept of risk classes. And this gives the opportunity to assess a medical device according to its risks.

As far as nomenclature is concerned, those familiar with medicines know that there is one language worldwide, which is called the international nonproprietary name. Every one knows, wherever in the world, what is Paracetamol, or whatever medicine you're talking about. That is not the case with medical devices. There is not one language to communicate when we are talking about medical devices. There are several medical devices nomenclature systems, which don't align, and that is causing a problem in regards to traceability and exchange of information

in case of a problem. There is a tendency towards GMDN but it has not been accepted world wide as the unique nomenclature system for medical devices.



## REGULATORY STATUS GLOBAL 2016

### Minute 00:15:13

This is a picture of the regulatory status of medical devices around the globe. It was a survey conducted in 2016 of all the WHO member states and it shows that only 58%, which is less than 2/3 of the countries, have some kind of medical device regulation in place. And that is worrying.



## REGULATORY STATUS GLOBAL 2016

**Minute 00:15:34**

If you look at the global map, especially in Africa there is no regulation and that means that large populations don't have access to medical devices of assured quality.



## Why...

- To allow for effective and safe medical devices
- To prevent medical devices of poor quality
- To prevent substandard and falsified medical devices
- To prevent direct harm to the patients
- To create level playing field for all stakeholders



The image contains several medical-related items: a syringe with green liquid, a patient lying on a surgical table with a large medical device above them, a coiled medical device with a screen, a glucose meter showing '58' next to a syringe, and a syringe lying on a blue fabric surface.

## WHY...

### Minute 00:15:52

Why would we need to regulate? First all we need regulation to allow for effective and safe medical devices for the patient and for the population. Secondly, regulation is important to prevent medical devices of poor quality and to intervene if necessary. Another reason is to prevent substandard and falsified medical devices. A number of 2008 from WHO, which is the most recent I came across, states that about 8% of medical devices on a global scale are falsified. And that can be a risk, not only for an individual, but for the population in general. If an HIV test or a tuberculosis test, for example, is of poor quality or falsified, which results in the wrong diagnosis it may affect a whole population.

A level playing field is also important because if there is no level playing field the bad guys benefit from the fact that there is no regulation and the good guys suffer from the bad guys in that regard.

## Regulating medical devices - challenges

- Less developed regulatory systems than for vaccines and medicines
- Lack of awareness
- Characteristics of medical devices as a product group
- Regulating in an existing market
- Lack of specialized knowledge and resources to draft and implement medical devices regulations
- Lack of resources

## REGULATING MEDICAL DEVICES - CHALLENGES

### Minute 00:17:15

So there are a number of challenges when we talk about regulating medical devices. The systems for regulating medical devices are less developed than the systems for vaccines and medicines. There is just little experience. There is also a lack of awareness. For example, if you just ask a person randomly what their idea of a medicine is, they probably have an idea and would say it is a tablet, a syrup, or whatever. If you ask them however what is a medical device is, they probably don't have a clear idea. They would probably say a CT scan but they don't have a clear idea of what a medical device is. That lack of awareness does not only exist in the general public but sometimes also applies to ministries or even within medicine departments of agencies.

The number and the characteristics of medical devices is of course a challenge. When countries starts regulating medical devices there are already tens of thousands, or even more, products on the market. How to start regulating when everything is already on the market? Due to the characteristics and variety of the group, it is also not easy for a regulator to know which expertise to have in-house and when to recruit expertise from outside the regulatory authority. A lack of resources, by the way, is a problem for any regulator worldwide.

## Regulating medical devices: way forward

- Classification into risk classes
- Classification based on the risk to patient, user or public health
- Essential Principles of safety and performance
- Involvement of Conformity Assessment Bodies (CABs)

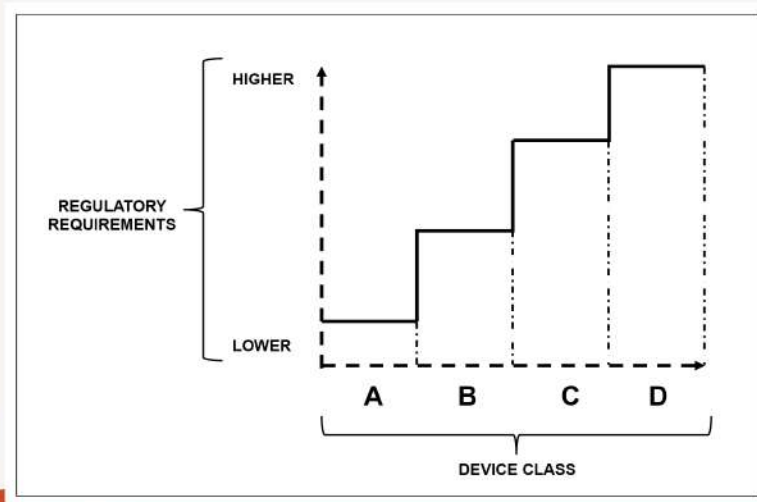
## REGULATING MEDICAL DEVICES – WAY FORWARD

### Minute 00:19:17

So what is the way forward? The way forward is a classification into risk classes and all the medical devices have to comply with what is called the Essential Principles of safety and performance. I will come back to that in a moment. And for a medical devices assessment, and that is specifically for medical devices, the involvement of conformity assessment bodies. A conformity assessment body is a body, which performs specific tasks on behalf of a regulatory authority or even has delegated regulatory powers, like the notified bodies in the EU. And that is very specific. Those are private enterprises but they have a role in the assessment of compliance for medical devices.

## Four risk classes: low- high

### Impact of device classification on regulatory scrutiny



## FOUR RISK CLASSES: LOW-HIGH

### Minute 00:20:16

Let us look at the risk classes. The risk classes determine what defines a risk class, which is in fact the potential to harm a patient. There are usually four risk classes, which are generally called A, B, C, D, or 1, 2, 3, 4 or 1, 2A, 2B, 3. The only country that I know of that has three classes is the US.

For the medical risk it is important to know how long the medical device stays in the body and its degree of invasiveness, so if it is really implanted in the body and if a medical device is lifesaving. For example, an ICD, which is an implanted defibrillator, is a high-risk device.

| Class | Risk          | Examples   |
|-------|---------------|--|
| A     | Low           | Syringes, examination gloves, patient hoists, stethoscopes, wheelchairs, IVD instruments, microbiological culture media  |
| B     | Low–moderate  | Surgical gloves, infusion sets, pregnancy tests  |
| C     | Moderate–high | Condoms (unless with spermicide (class D)), infusion pumps, neonatal incubators, therapeutic and diagnostic X-ray, lung ventilators, haemodialysers, anaesthesia equipment, self-test glucose strips, IVDs for the diagnosis of Neisseria gonorrhoea |
| D     | High          | Implantable cardioverter defibrillators, pacemakers, breast implants, angioplasty balloon catheters, spinal needle, IVDs for the diagnosis of HIV, hepatitis C or hepatitis B  |

## RISK CLASSES

### Minute 00:21:14

These are just some examples of low and high-risk devices. Low-risk devices are, for example, syringes or IVD instruments. On the other hand the tests for some diseases that cannot be cured, are high-risk devices. Condoms, for example, are classified as moderate risk but with spermicide then they are qualified as high-risk. So to know how this is working in practice, the manufacturer establishes, based on certain rules, which are specified in the guidelines, the risk class of a medical device. And the authority can always challenge this risk classification by the manufacturer. And that is also different for medicines where the regulator usually establishes “prescription only” or “over-the-counter” status of a medicine.

## Essential principles of safety and performance

- The processes for the design and production should ensure that a medical device **when used according to the intended purpose** and meeting the conditions of **technical knowledge and training of the user** is safe and does not compromise the clinical condition of the patient or the health of the user.
- Medical devices should perform as the manufacturer intended **under normal conditions**
- The manufacturer should perform **a risk assessment** to identify known and foreseeable risks and to mitigate these risks in the design, production and use of the medical device.

## ESSENTIAL PRINCIPLES OF SAFETY AND PERFORMANCE

### Minute 00:22:17

This slide is related to the essential principles. All medical devices should comply with the essential principles of safety and performance. The essential principles, in fact, include the design and the process of a medical device. When a medical device is used under normal conditions and according to the intended purpose, it should not jeopardize or compromise the clinical condition or safety of the patient. Please keep this in mind because I will mention, at a later point of the webinar, some serious adverse events happening with medical devices and then you can check how they meet this requirement on the essential principles of safety and performance. Any medical device, of course, has residual risks. But the risk should be mitigated by the manufacturer to an acceptable level.

## Conformity assessment

- Is determined by the risk class
- Low risk class: self-certification and notification to the authorities
- Technical documentation: premarket submission not required for class A, no premarket review for class B to in depth review for class D.
- QMS is always required
- Higher risk classes: from confidence in the QMS of the manufacturer to full QMS audit for class D
- Declaration of conformity: issued by the manufacturer.

## CONFORMITY ASSESSMENT

### Minute 00:23:31

So the manufacturer is responsible for compliance but the authority is going to assess the medical device to check if what has been stated by the manufacturer is really true. However, this is not the case for the low risk devices, only for high-risk devices. The involvement of the regulator is higher with a high-risk device and lower with a low-risk device. The low risk devices, which are class A, require certification and notification. In most countries there is a system of notification. This means that the manufacturer or importer notifies the regulatory authority that he is marketing a class A medical device and he does not need to submit any technical dossier. By the way, the regulator always has the power to check or to intervene in case of a problem. For a class D device, a full review of the technical dossier is required.

## Conformity assessment processes as determined by device class

| Conformity assessment element   | Class A  | Class B   | Class C   | Class D   |
|---------------------------------|--|---|---|---|
| Quality management system (QMS) | Regulatory audit normally not required, except where assurance of sterility or accuracy of the measuring function is required. | The regulatory authority should have confidence that a current and appropriate QMS is in place or otherwise conduct a QMS audit prior to marketing authorization.                   | The regulatory authority should have confidence that a current and appropriate QMS is in place or otherwise conduct a QMS audit prior to marketing authorization. | The regulatory authority should have confidence that a current and appropriate QMS is in place or otherwise conduct a QMS audit prior to marketing authorization. |
| Technical documentation         | Premarket submission normally not requested.   | Not normally reviewed premarket. The regulatory authority may request and conduct a premarket or postmarketing review sufficient to determine conformity with Essential Principles. | The regulatory authority will undertake a review sufficient to determine conformity with Essential Principles prior to the device being placed on the market.     | The regulatory authority will undertake an in-depth review to determine conformity with Essential Principles, prior to the device being placed on the market.     |
| Declaration of conformity       | Submission normally not requested.   | Review and verify compliance with requirements by the regulatory authority (see footnote to Table A4.1).  | Review and verify compliance with requirements by the regulatory authority (see footnote to Table A4.1).  | Review and verify compliance with requirements by the regulatory authority (see footnote to Table A4.1).  |

[https://www.who.int/medical\\_devices/publications/global\\_model\\_regulatory\\_framework\\_meddevices](https://www.who.int/medical_devices/publications/global_model_regulatory_framework_meddevices)

## CONFORMITY ASSESSMENT

### Minute 00:24:56

This is a summary of the conformity assessment processes by the regulatory authority for class A, B, C and for class D, which requires an in-depth review to determine the conformity with the regulatory requirements. So in class A it is mainly self-certification and notification while in class D it is a full blown assessment by the regulatory authority, or in Europe by a notified body.



## Regulating medical devices

### 1. Common approach: stepwise

- Legal framework: definition, risk classes, essential principles of quality and performance, quality system, declaration of conformity
- Specify a transition period
- Designate a regulatory authority
- Develop a procedure for exceptional premarket situations
- Perform a gap analysis

[https://www.who.int/medical\\_devices/publications/global\\_model\\_regulatory\\_framework\\_meddev/en/](https://www.who.int/medical_devices/publications/global_model_regulatory_framework_meddev/en/)  
<http://apps.who.int/medicinedocs/documents/s22503en/s22503en.pdf>  
<http://www.imdrf.org/docs/ghrf/final/steering-committee/technical-docs/ghrf-sc-n1r13-2011-ad-hoc-regulatory-model-110413.pdf>  
[http://www.ahwp.info/sites/default/files/ahwp-files/4\\_Technical\\_Committee/AHWP%20Playbook%20for%20Implementation%20of%20MD%20Reg%20Framework.pdf](http://www.ahwp.info/sites/default/files/ahwp-files/4_Technical_Committee/AHWP%20Playbook%20for%20Implementation%20of%20MD%20Reg%20Framework.pdf)

## REGULATING MEDICAL DEVICES

### Minute 00:25:24

Those are the principles, but how to start in a country where there is no regulatory system in place? There is a common approach by a number of international bodies, like WHO and the Asian Harmonization Working Party.

The first step is to make a legal framework to see what we are talking about and what we are regulating and to establish a definition, risk classes, essential principles of quality and performance and to make it a solid legal framework. It is also important to specify a transition period, which allows the industry or healthcare to adapt to the new situation, especially when there is no regulation. Another aspect is to design and empower a regulatory authority. And there will always be exceptions so there should be a process in place to handle those exceptions. For instance, if there is a very specific condition of one patient, it is important to know how to deal with it and how can we bring that into the country. And of course it is essential to perform a gap analysis to determine where you want to go, what you have in place what are the gaps.

## Regulating medical devices

### 2. Common approach: market oversight and vigilance system

- Create market oversight: registration of establishments and listing of medical devices
- Establish a reporting system for serious adverse events and quality problems
- Monitor manufacturers, importers, distributors (and Authorized Representatives) reporting and taking corrective action
- Create possibility for recall and suspending marketing authorization

## REGULATING MEDICAL DEVICES

### Minute 00:26:58

So first you establish a regulatory framework and then the next step is that you would want to know what is happening on your market. Who is bringing medical devices into the country? And what are the medical devices they place on the market? So you could ask them to register their establishment and submit an updated list of the medical devices on the market. It is also important that there is a vigilance system or a reporting system in case of a problem, so that both the manufacturer and the authority know what is happening and that they can act, intervene or follow up a program. And for those of you who are familiar with medicines, you know that it is the same. If there is a serious adverse event in medicines there is also the corrective action needed by the manufacture and, if needed, a recall of the product.

## Regulating medical devices

### 3. Common approach: authorizing medical devices

- Establish a procedure for authorizing medical devices to be placed on the local market
- Set priorities for performing inspections
- Establish testing priorities and facilities
- Recognize standards
- Create oversight of clinical investigations
- Accept a nomenclature system
- Etc.
- Etc.

## REGULATING MEDICAL DEVICES

### Minute 00:28:20

After a country has the power, the legal framework and the market oversight including the vigilance system, the third step could be the development of a register system for medical devices, for individual devices, to perform inspections on site, to have oversight of clinical investigations in the country etc. It depends, of course, also on the situation in the country. If there are no clinical investigations being performed in the country then you would not prioritize that, but if there are you would.



|   |   |  |
|---|---|--|
| 1. Commit to whole-of-government policy for regulatory quality  | 2. Adhere to principles of open government  | 3. Provide oversight of regulatory policy  |
| 4. Integrate regulatory impact assessment   | 5. Conduct systematic programme reviews of regulatory stok  | 6. Regularly publish reports on performace of regulatory policy                                      |
| <b>7. Develop a consistent policy covering the role of regulatory agencies</b>  | 8. Ensure effectiveness of systems for review of legality and procedural fairness                 | 9. As appropriate apply risk assesment, risk management, and risk communication strategies           |
| <b>10. Where appropriate promote regulatory coherence through co-ordination mechanisms between levels of government</b> | 11. Foster the development of regulatory management capacity at sub-national levels of government | <b>12. Give consideration to all relevant international standards and frameworks for cooperation</b> |

## ENABLING CONDITIONS FOR REGULATING

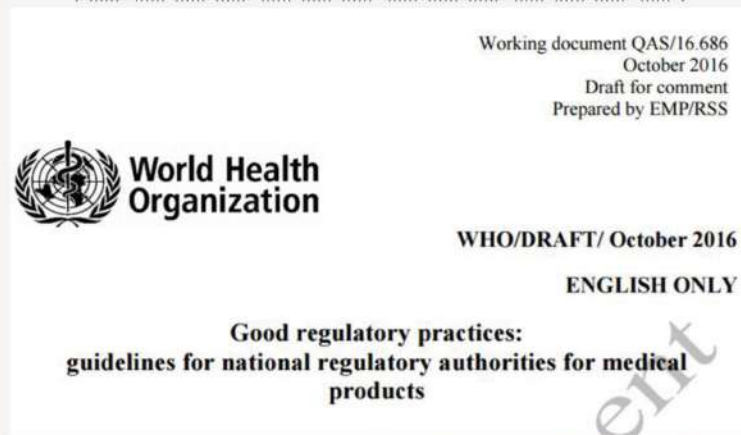
### Minute 00:29:43

And here they are. I will point out three of them. Number 7 states that the regulatory authority for medical devices needs a consistent support from the government to be able to control and, if needed, to enforce the regulatory requirements. Agencies may need to intervene, which is not always welcomed by the industry. Also in some cases companies go to the Minister and say that they don't agree with the agency and ask the ministry to intervene. In such cases the agency needs support from politics and politicians.

Number 10 states that in many countries there are regions, states or provinces with legal power. In countries like Germany, for instance, or India or in China where there are different regions, a coherent regulatory process throughout the country is needed should be a reliable partner for stakeholders. Because you make a life of stakeholders very difficult if there are several different requirements in provinces or regions.

The number 12 on this chart is about international harmonization. In a global market like to medical devices market sticking to international standards is efficient and effective and makes life easier for everyone.

## Good regulatory practices: medical products



[http://www.who.int/medicines/areas/quality\\_safety/quality\\_assurance/GoodRegulatory\\_PracticesPublicConsult.pdf?ua=1](http://www.who.int/medicines/areas/quality_safety/quality_assurance/GoodRegulatory_PracticesPublicConsult.pdf?ua=1)

## GOOD REGULATORY PRACTICES: MEDICAL PRODUCTS

### Minute 00:31:22

WHO, based on the OECD guidelines, developed good regulatory practices focused on medical products. It is still a draft but I think it is a good document.

## Good regulatory practices: medical products

- Critical elements for regulating medical devices
  - Political commitment
  - Legal framework
  - Implementation plan
  - Competent authority with enforcement power
  - Involvement of stakeholders
  - Transparent and impartial
  - Performance evaluation
- Importance of convergence, harmonization, **reliance and recognition**

## GOOD REGULATORY PRACTICES: MEDICAL PRODUCTS

### Minute 00:31:35

They list a number of critical elements but I would like to focus on the reliance and recognition. Reliance and recognition are concepts that contribute to the efficient implementation of regulation. The thinking behind is not to duplicate what someone else has already done or what someone else can do better. For example, if a medical device is approved by the USFDA and on the market in the US, what could a regulator in another country add to the work of USFDA? Why not accept that product, and in fact it is their regulatory decision, for their market in their country?

## Reliance

The act whereby the NRA in one jurisdiction **may take into account and give significant weight to** – i.e., totally or partially rely upon – evaluations performed by another NRA or trusted institution in reaching its own decision. The **relying authority remains responsible and accountable** for decisions taken, even when it relies on the decisions and information of others.

## RELIANCE

### Minute 00:32:30

Reliance means taking the information and giving it significant weight but making your own regulatory decision.



## Recognition

The **routine acceptance** by the NRA in one jurisdiction **of the regulatory decision of another NRA** or other trusted institution. Recognition indicates that evidence of conformity with the regulatory requirements of country A is sufficient to meet the regulatory requirements of country B. **Recognition may be unilateral or multilateral**, and may be the subject of a mutual recognition agreement.

## RECOGNITION

### Minute 00:32:50

Recognition, on the other hand, goes one step further. It is the routine acceptance of the regulatory decision of another jurisdiction. There are recognition agreements between mature authorities, like the EU and Switzerland, for instance. For medical devices there is a complete open market between Switzerland and the EU. The same applies to the EU and Australia. There could also be a unilateral recognition, for instance SAUDI Food and Drug Administration recognizes the products marketed by Canada, US, EU, Japan and Australia.

## Conditions for reliance and recognitions

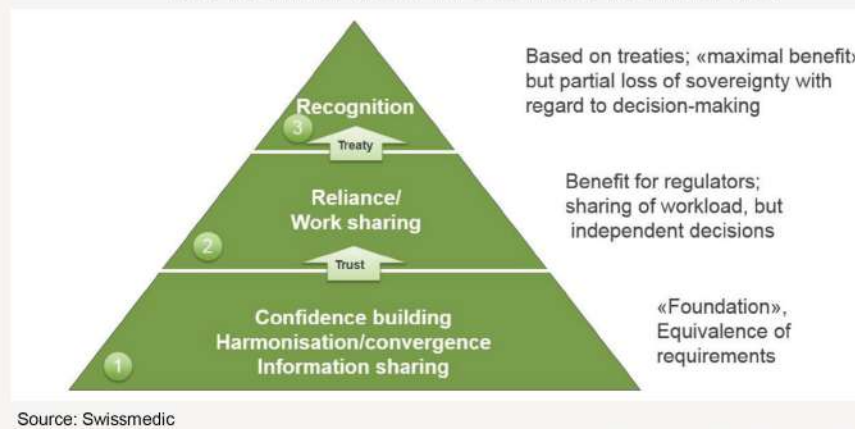
- The legal framework basis that allows the regulatory authority to apply the principles of “recognition”
- A clear understanding of the regulatory system that applies within the country where the medical device is manufactured.
- Certain regulatory activities are inherently only within the competence of the national authority

## CONDITIONS FOR RELIANCE AND RECOGNITION

### Minute 00:33:43

There are some conditions, of course, because if you rely on a regulatory decision of another country, it should be in the law. Also you would need to have a more or less similar regulatory framework as a country of origin and to know the details of this other country. I will give you an example. In 2017 the EU adopted a new regulation for medical devices. It is substantially stricter than the current medical device directive. So if a country accepts a medical device with a CE marking, it should know whether it is based on the medical device directive from 1993 or on the new medical device regulation. Certain regulatory activities you can't outsource or you cannot rely on or recognize. Those include import controls, distribution and vigilance. If there is a serious adverse event or you have a problem in your country you can't rely on someone else and then the regulatory authority is in charge.

## Reliance and recognition



## RELIANCE AND RECOGNITION

### Minute 00:35:15

This is a diagram showing the steps, from confidence building to harmonization, reliance and work sharing, and recognition. Recognition is indeed a partial loss of sovereignty with regards to decision making of a country. So you really need a legal basis to do this. Then again, no agency can do all the work by themselves. Parts are being outsourced to quality assessment bodies or accepted from other jurisdictions.

## International harmonization



**IMDRF** International Medical  
Device Regulators Forum

- International Medical Device Regulators Forum (IMDRF).
- Until 2011 GHTF
- 10 member jurisdictions: Australia, Brazil, Canada, China, European Union, Japan, Russia, Singapore, South Korea, USA
- Development of guidance documents

<http://www.imdrf.org/>

## INTERNATIONAL HARMONIZATION

### Minute 00:35:55

I have mentioned the importance of aligning with international standards. Therefore, I will show you some slides on international harmonizing bodies. I think the most important is the International Medical Device Regulators Forum. The IMDRF is important in developing harmonized guidelines. It started in 2011 and it is the successor of the Global Harmonization Task Force, which was established in 1993 already. If you want to have access to their website you can have access to many documents. The documents that IMDRF develops are always out for public consultation so you can give them feedback.

## International organizations for standardization



IMDRF

Optimizing Standards for Regulatory Use

Authoring Group: IMDRF Standards Working Group

Date: 5 November 2018

<https://www.iso.org/home.html>

<https://www.iso.org/committee/54892.html> (TC210)

<http://www.iec.ch/>

[www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-181105-optimizing-standards-n81.pdf](http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-181105-optimizing-standards-n81.pdf)

## INTERNATIONAL ORGANIZATIONS FOR STANDARDIZATION

### Minute 00:36:55

Unlike medicines, where regulatory authorities develop standards, for medical devices ISO and the International Electro-technical Committee (IEC) are important bodies for the development of standards. Currently IMDRF is taking part in developing the standards. Unfortunately the standards from ISO and IEC are not available for free. You have to buy them but they are indispensable for both regulators and Industry.

## Guidance by WHO

| Number of guidance documents developed by WHO | medicines   | medical devices   |
|---|---|---|
|   | <ul style="list-style-type: none"> <li>&gt; 75 general QA standards, good practices, guidelines</li> <li>625 test specifications included in the International Pharmacopeia</li> <li>&gt; 200 international chemical reference standards</li> </ul> | good review practices for medicines and medical devices |
|   | blood products  |   |
|   | < 10 guidelines   | IVDs as part of PQ                                      |
|   | biotherapeutics including vaccines  |   |
|   | 7 general documents for both vaccines and biotherapeutics<br>8 general documents all vaccines<br>5 biotherapeutic specific<br>57 vaccine specific   |   |

## GUIDANCE BY WHO

### Minute 00:37:32

WHO developed a limited number of standards for medical devices and they are all part of the pre-qualification program and focus on IVD diagnostics.

# When

|                      | Medicines     | Medical devices                            |
|----------------------|---------------|--|
| Regulatory framework | All countries | 58% of countries for MDs,<br>Less for IVDs |

## Beginning of Regulatory Controls

|    | Medicines | Medical devices |
|----|-----------|-----------------|
| US | 1937      | 1976            |
| EU | 1965      | 1993            |

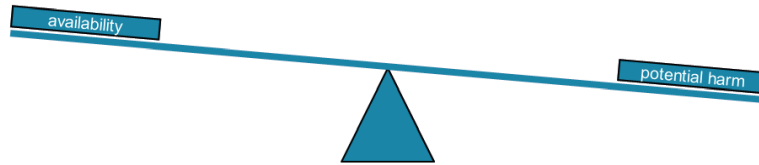


## WHEN

### Minute 00:37:56

Now we will talk about when to regulate. We have talked about what, why, and how and now we will look into when to regulate medical devices. Mature jurisdictions of the US and the EU started regulating medical devices about 30 years after medicines. You can see that. In most cases the trigger to regulate was a disaster. For medicines in the US it was a toxic cough syrup. In Europe it was the Thalidomide disaster. For medical devices the Björk–Shiley heart valve, which caused sudden death in some patients, was the trigger. And of course the latest review of a new regulatory framework in Europe was triggered by the scandal of breast implants.

## Balancing interests



A public health approach recognises that the potential good of a new medical product or policy must be balanced against the potential harm.<sup>1\*</sup>

- How to balance risk and availability?
- How to concentrate on high risk?
- How to detect unknown risk?

<sup>1</sup>Margaret Hamburg, NEJM 360, 24, June 11, 2009

## BALANCING INTERESTS

### Minute 00:38:54

Regarding the approval of medical products there is always this dilemma of balancing interests, of balancing between availability and safety. 100% safety does not exist. So the question will always be how to balance risk and availability, how to concentrate on high risk, and how to detect unknown risks. In my view, this would require a responsive system of reporting and acting upon the first events happening by the healthcare system, the user, the manufacturer and by the regulator.



## Serious adverse events or serious public health threats

### **80,000 Deaths. 2 Million Injuries. It's Time for a Reckoning on Medical Devices.**

Patients suffer as the F.D.A. fails to adequately screen or monitor products.

In the past decade, nearly two million injuries and more than 80,000 deaths have been linked to faulty medical devices, many approved with little to no clinical testing, according to a global investigation by the International Consortium of Investigative Journalists.

Dr. Jeffrey Shuren, head of the agency office in charge of device regulation, has suggested that the benefits of bringing innovative products to market quickly are worth the increased risks.

<https://www.nytimes.com/2019/05/04/opinion/sunday/medical-devices.html>

## **SERIOUS ADVERSE EVENTS OR SERIOUS PUBLIC HEALTH THREATS**

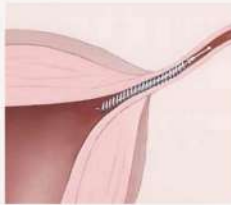
### **Minute 00:39:51**

Serious adverse events may be a public health threat. This is a recent publication from early May of this year, by the New York Times, prepared by a group of journalists. They detected 80,000 people dying over a decade, so 8000 per year as an average in that US alone, linked to medical devices. This means that, in all countries, authorities, industry and the healthcare system have the responsibility to be alert and to act in a responsive way. Because if you don't you can't stop an adverse event from happening.

## Serious adverse events



<https://www.fda.gov/medicaldevices/productsandmedicalprocedures/implantsandprosthetics/metalonmetalhipimplants/ucm241604.htm>



<http://www.essure.com/>  
<https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/EssurePermanentBirthControl/default.htm>



[https://www.camd-europe.eu/wp-content/uploads/2018/05/JAMS\\_Information-for-notified-bodies-1.pdf](https://www.camd-europe.eu/wp-content/uploads/2018/05/JAMS_Information-for-notified-bodies-1.pdf)



<https://www.fda.gov/medicaldevices/productsandmedicalprocedures/implantsandprosthetics/gyn/surgicalmesh/>

## SERIOUS ADVERSE EVENTS

### Minute 00:40:35

These are examples you may know. I have already mentioned before the essential principle of not harming the patients. But these products did. This is the metal on metal hip implant. It caused soft tissue damage to more than 10% off the patients with this implant. And another example is the Essure contraceptive, which was marketed as an effective, simple and safe contraceptive. But worldwide it caused a number of women really big problems, like abdominal pain, vaginal bleeding, blood loss and even becoming pregnant. The discussion about breast implants started years ago but there is still an ongoing research on the long-term effects of breast implants. And another example is a vaginal mesh, a medical device used in women with prolapse. If not implanted in the correct way it inhibits women in performing their daily activity without pain.

## Trademark counterfeiting

مقلد  
Counterfeit



stainless steel  
CE

Genuine  
أصلي



Stainless steel  
Germany  
CE

Nazeeh AlOthmany, PhD, SFDA

[https://www.who.int/medical\\_devices/global\\_forum/3rd\\_gfmd/againstcounterfittingforgingdocuments.pdf](https://www.who.int/medical_devices/global_forum/3rd_gfmd/againstcounterfittingforgingdocuments.pdf)

## TRADEMARK COUNTERFEITING

### Minute 00:42:15

These are some other examples, which you would not want to have on your market. These are linked to trademark counterfeiting. The examples I show are all seized by SFDA. It is very difficult to detect which is the genuine and which is the counterfeit. On one device it says "stainless steel" and on the other device it says "stainless steel Germany". This was captured by port Inspectors when compared with the original product. This was a very good port inspector, I would say.

# Trademark counterfeiting

Genuine

Counterfeit



## TRADEMARK COUNTERFEITING

Minute 00:43:03

These are sugar strips. The authorized representative of the genuine product reported counterfeit products on the market. They investigated and indeed it was a counterfeit, but again this is very difficult to detect if you don't have the two of them on the same table.

## Trademark counterfeiting

Counterfeit

Genuine



## TRADEMARK COUNTERFEITING

**Minute 00:43:23**

This is the last example I will show you. This is a stethoscope. And again you can see the genuine and the counterfeit.

## Declaración de la misión del MINSAL de Chile

*La misión de este ministerio es construir un modelo de salud sobre la base de una atención primaria fortalecida e integrada, que pone al paciente en el centro, con énfasis en el cuidado de poblaciones durante todo el ciclo de vida, y que además estimule la promoción y prevención en salud, así como el seguimiento, trazabilidad y cobertura financiera.*

<https://www.minsal.cl/mision-y-vision/>

## DECLARACIÓN DE LA MISIÓN DEL MINSAL DE CHILE

### Minute 00:43:38

The last part of this webinar will be dedicated to Chile. This is the mission statement of MINSAL, the Ministry of Health in Chile. It is about access to healthcare but also promoting good health care. Regulating medical devices is about protecting public health and can be considered part of this mission statement.

## Regulating medical devices in Chile: current status

Medical devices are regulated

- Surgical gloves
  - Hypodermic needles, sterile, single use
  - Hypodermic syringes, sterile, single use
  - Male condoms, latex and synthetic
  - Female condoms
- 
- 95% of medical devices are imported, mainly from USA and EU
  - Import controls by customs

<https://www.leychile.cl/Navegar?idNorma=141005>  
<https://www.leychile.cl/Navegar?idNorma=225470>  
<https://www.leychile.cl/Navegar?idNorma=268987>  
<https://www.leychile.cl/Navegar?idNorma=1121083>

## REGULATING MEDICAL DEVICES IN CHILE

### Minute 00:44:03

So what is the current status of regulating medical devices in Chile? A limited number of devices is now being regulated. Here you can see the regulated devices. 95% of medical devices are imported, mainly from the US and the EU. The import controls are performed by customs. They send reports of what is coming into the country to ISP.

## Chile: regulating medical devices: developments

- Regulation
  - Ley de Fármacos II (Código sanitario, Article 111\*) has been amended
  - Reglamento de Dispositivos Médicos has been developed
- Guidance documents
  - Essential Principles of safety and performance (published)
  - Classification of medical devices (published)
  - Technovigilance
  - Clinical evaluation
  - Clinical investigation
  - Good distribution practices
  - STED

\* <https://www.leychile.cl/Navegar?idNorma=1058373>

## REGULATING MEDICAL DEVICES IN CHILE

### Minute 00:44:38

As far as the legal framework is concerned, the Ley de Fármacos has been amended, which is based on the Código Sanitario. The Ley de Fármacos contains the regulatory basis for medical devices regulation. The Reglamento de Dispositivos Médicos has been developed and it details more of the requirements. And a number of important guidance documents have been developed and some of them have been published. So the regulatory framework has been developed.



## Chile: harmonized regulatory requirements

- Regulation is aligned with international standards
  - Definitions
  - Essential Principles of safety and performance
  - Labelling of medical devices
  - Risk classes
  - Quality management system
  - ISO standards

## CHILE: HARMONIZED REGULATORY REQUIREMENTS

### Minute 00:45:15

I think they did a good job because they looked at the international standards regarding definitions, essential principles and labeling risk, which means it makes recognition of regulatory decisions of other jurisdictions such as the US, Europe possible. So they can recognize the products marketed in those jurisdictions.



## WINDOW OF OPPORTUNITY

### Minute 00:45:40

There is a concept called a window of opportunity. Let me show you. If you have a problem, if you have a solution, and if you have political events, which are happening, where ever those three lines cross you could say that there is a window of opportunity. And that is what happened in Chile. The problem was that the law was lagging behind. There was a solution and an example of a legal framework developed by the WHO and they received the support of The Inter-American Development Bank. And a political event was the modification of the Ley de Fármacos.

## Chile: regulating medical devices: implementation

- Opportunities
  - ISP is the established regulatory authority
  - Dedicated team
  - Increasing awareness at political level
  - Support by BID
  - Support by stakeholders
- Challenges
  - Approval of the Ley de Fármacos II by Congress
  - Acknowledging medical devices as a product group
  - Resources

<http://www.ispch.cl/temas/medicos>

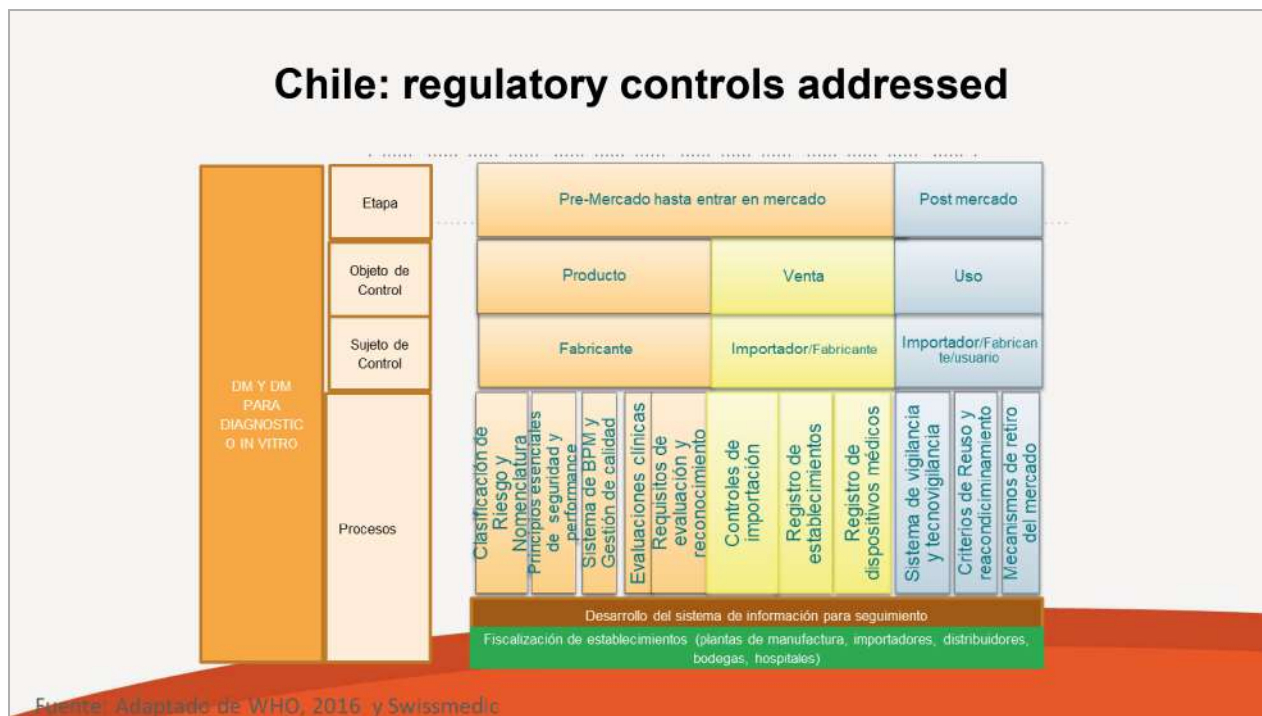
## CHILE: REGULATING MEDICAL DEVICES

### Minute 00:46:36

When we are looking at Chile the opportunities are the following. ISP, which is the regulatory authority, is established as the regulatory authority. It consists of a dedicated team. There is also increasing awareness at the political level and support by BID, as well as support by stakeholders. ISP is organizing what they call the "mesa de trabajo" and they are involved in the discussions on what the technical requirements are and how we can proceed with the industry. It is very good to have their support.

There are also challenges. The first one is a big challenge. The Ley de Fármacos has not been adopted by Congress yet. It has not passed. And that is a hurdle. ISP is working on making the documents ready but if the law doesn't get approved they will come to a kind of standstill, I think, and that would be a pity for all the effort that ISP has been putting there. Another aspect is acknowledging medical devices as a product group. Still some people think that the "medicine system", as I would you call it, is also applicable to medical devices which is not the case. I hope I explained that sufficiently. And of course there is the lack of resources. How many resources do we need and what kind of resources? What kind of expertise do you need in your agency?

## Chile: regulatory controls addressed



## CHILE: REGULATORY CONTROLS ADDRESSED

### Minute 00:48:22

These are the regulatory controls currently addressed in Chile. First you see the stage, which is pre-market and entering on the market as well as post market. The second row shows the object of control which is the product and the sales in the pre-market and when entering the market, and use in the post market.

The third row shows the responsible party, which is the manufacturer and importer in the pre-market and then at market entry and in the post market the importer and the user. And the last row shows the regulatory processes. The processes that have been developed include the classification, the principles, the QMS system, as well as your requirements for recognition. After that you can see the market oversight and the post market activities of the vigilance system. And of course cross cutting are also inspecting activities.

## Regulating medical devices insufficiently (1)

- Medical devices including falsified medical devices can be placed on the market that do not comply with the Essential Principles of safety and performance.
- Health care providers cannot assure to patients that the medical devices used in health care are of good quality.
- Patients and consumers can be affected negatively.
- Lack of level playing field: reliable manufacturers tend to comply with regulatory requirements in the country of origin. Non-reliable enterprises can place medical devices of poor quality and falsified medical devices on the market without repercussion.

## REGULATING MEDICAL DEVICES INSUFFICIENTLY

### Minute 00:49:29

So what would happen to Chile, and what would happen to any country if they don't regulate medical devices or regulate them insufficiently? Medical devices, including falsified devices, can be placed on the market even if they do not comply with the essential principles of safety and performance. Healthcare providers cannot assure to patients the quality of medical devices they use, and they use medical devices in every intervention. Patients and consumers can be affected negatively. Another aspect is the lack of a level playing field. Reliable manufacturers tend to comply with regulatory requirements in the country of origin. But non-reliable enterprises can place medical devices of poor quality on the market without any repercussion.

## Regulating medical devices insufficiently (2)

- The government through the regulatory authority is not in the position to protect public health.
- The regulatory authority is not in the position
  - to monitor the compliance of manufacturers with regulatory requirements
  - enforce in case of (serious) non-compliance.
- In case of serious adverse events in health care where a medical device is involved the regulatory authority may not be in the position to act to prevent similar cases happening.
- Public trust in the regulatory authority and the ministry may become at stake

## REGULATING MEDICAL DEVICES INSUFFICIENTLY

### Minute 00:50:21

Furthermore, the government through the regulatory authority is not in the position to protect public health. At the same time the regulatory authority is not in the position to monitor the compliance or to enforce inactivity in the case of serious noncompliance. In the case of serious adverse events in healthcare the regulatory authority may not be in the position to prevent further cases from happening. So you can't stop a serious adverse event from happening again. And one aspect, which is probably the most difficult to tackle, is public trust in the regulatory authority, in the ministry, and perhaps even in the government.

## Regulating medical devices

**WHY: to protect public health**

**WHAT: medical devices (and borderline products?)**

**HOW: good regulatory practice**

**WHEN: now and benefit from a window of opportunity**

## REGULATING MEDICAL DEVICES

### Minute 00:51:12

In summary, why do we need to regulate medical devices? The reason is to protect public health. What are we going to regulate? We are going to regulate medical devices. Does this also include borderline products? How are we going to do this? According to a good regulatory practice. And lastly, when should we regulate medical devices? We should regulate them now and benefit from a window of opportunity if possible.

## QUESTIONS & ANSWERS

### Minute 00:52:15

#### *Question by Yvette:*

***How do regulating agencies of medical devices ensure that the medical devices that are approved are safe for the patients, for the doctors, and for the environment? For example, are the manufacturers asked for tests regarding mechanical resistance or simulations in order for the medical devices to be approved?***

#### *Answer by Josée:*

As I said, all the medical devices have to comply with essential requirements. And if you look at essential requirements, which are normally in an annex of a regulation, or you can find checklist where they are specified, the manufacturer has to state how he is going to comply with any specific essential requirements. This includes the materials he is using, the bio-compatibility if needed. And if anything doesn't apply to his medical device he should state "not applicable". In case that it does apply, he has to explain how he proves that it does comply and specify the norm and standard to which the medical device is tested.

### Minute 00:54:15

#### *Question:*

***In countries with a high number of small and middle-sized manufacturers of medical devices, how can the topic of clinical research required be tackled without affecting their economic viability?***

#### *Answer by Josée:*

First of all I think that nobody wants double standards. That is always a challenge. You can't say that because someone does not have the financial power to perform a clinical investigation or a certain test we can allow for less. I think that is hardly acceptable. This is a very political issue but I don't think any politician or any agency would say that they accept less if it is a domestic or a small manufacture.

So what you can ask for is sufficient clinical evidence. In Europe, in the current medical device directive this so-called bibliographic evidence is also considered to be sufficient. So you can ask what is sufficient to prove the clinical evidence, the safety and the compliance with essential



principles for a medical device. But I think I would not promote double standards just because somebody someone is not in the financial position to provide all the evidence. Because if you allow small amount manufacturers to do that, why would bigger manufacturers need to comply? So I would say one way is to provide guidance on how clinical evidence can be proved, which can also include bibliographic evidence. Solid bibliographic evidence could in some cases be sufficient.

**Question by Yvette:**

***Which international references regarding regulation of devices did Chile take into account?***

**Answer by Josée:**

For example regarding the definition of risk classes, Chile took the documents of the IRDAF. So they took the definition of risk classes and principles of safety as a basis. For instance for the quality management system, which is a famous ISO standard (standard 13485), they took this standard as the established standard for the quality management system. So as much as possible they took internationally harmonized standards.

**Question:**

***Is it possible to talk about a universal system to identify risks related to medical devices of the same class, category, or family?***

**Answer by Josée:**

In the medical device regulation there are a number of flow charts or guidances on how to classify a medical device, whether it is low risk class etc. In fact, it is checking a number of requirements and than that results in a certain classification, like low, medium or a high-risk class. This is included in guidance documents from regulators. Sometimes there is a reclassification. For example, hip implants in Europe are classified as class 2B, which is class medium-high. And now they are class 3, which is the highest risk class. So there is also development. Once it turns out that a medical device can have a higher risk than anticipated, it may be reclassified.

**Question by Roberto:**

***How can the quality of medical devices be defined? Is it defined through a certain measure or certain implicit characteristics of the device?***

**Answer by Josée:**

The quality is defined by the essential principles. So they have to comply with essential principles and then it depends on the design and the production what quality means. There is a technical dossier including all the requirements which have been developed and also during production. For example, an IVD requires a certain level of specificity or sensitivity. I can't answer this in general terms. The general approach is related to the essential principles and in the technical documentation the manufacturer establishes the range of tests and testing results.

**Question by Yvette:**

***Is there any country that is already regulating new technologies such as software, apps, or medical devices with nanotechnology? If so, is it a successful example to observe?***

**Answer by Josée:**

Yes there is. I would refer to both IMDRF and USFDA websites because there are some documents called software as a medical device and there is even a document, which is called the clinical evaluation of software. So USFDA is definitely regulating them and Europe as well. So there are jurisdictions where they are regulated but of course there is a thin line whether it is a medical device software or not. There are documents and as a step further, which is now under development by IMDRF, there is a document regarding cyber security. Because software could be vulnerable to cyber attacks it could also affect the safety of the medical device. Again if you go to the IMDRF website, under documents you're find this information on software as a medical device.

**Question by Alfredo:**

***What is the percentage of illegal trade of counterfeit medical devices?***

**Answer by Josée:**

We don't know. I mentioned the WHO figure from 2008, which states 8%, but unfortunately medical devices we don't have such an overview as we have for medicines. WHO has a department for falsified and sub-standard products but they focus mostly on medicines. The examples I showed are quiet consistent in tracking down falsified products but so far there are only examples. There are examples of falsified condoms, falsified lenses etc. but unfortunately we don't know the percentages. I think that is also why countries in Europe have to stay alert regarding the introduction of counterfeit, substandard medical devices.

**Comment by Stephanie:**

I think also in Latin America it is a bit difficult to know the percentage due to the lack of regulation of medical devices in the region. There is no data to observe this.

**Question by Marcela:**

***Are there any countries which are using analytical methods to decide which medical devices should be funded by the public sector?***

**Answer by Josée:**

I am not a specialist in health technology assessment. I noticed from the health technology assessment the majority of the HTA assessments are on medicines and only a limited number on medical devices. Honestly, I think that Adriana Velazquez who is working at the WHO is more an expert on this than I am. I would like to pass on this question since I'm not an expert in HTA.

**Question by Ursula:**

***Since the countries cannot do everything by themselves it would be good to have a regional alliance to regulate medical devices in Latin America. Do you think this would make sense?***

**Answer by Josée:**

Yes, I am very much in favor. It is not an easy task. As you know, I am from Europe, and to harmonize and align all the countries, which means 28 countries, is not easy. But it is worthwhile because in the end it pays off. It is good to align it and it makes life easier for the regulators and also more efficient, but you have to trust each other. This is why I showed the slide on reliance and

recognition, which shows that the process starts with confidence building. Confidence building is the first step. You have to trust each other. If you don't trust each other it is very difficult, but in the end it pays off because it is more efficient to collaborate and to have the same set of rules so that products can move between countries without the hurdle of an extra regulatory control.

**Comment by Stephanie:**

I think in Latin America the Alianza Pacífica could be a first step to start an alliance of this kind.

**Question:**

***Is the maintenance of biomedical equipment being controlled and monitored? Which level of regulation is considered as low? There are a lot of hospitals which do not measure the degree of degradation of biomedical equipment.***

**Answer by Josée:**

In fact the question is to what extent the manufacturer is responsible. Because once a piece of equipment is sold, you can't say that the hospital is responsible, but of course they need instructions for use and they also need maintenance. That part is called health technology management. In that case to hospital or the healthcare institution should make a contract with a manufacturer regarding who is responsible for maintenance and how long this maintenance contract can last. Because if not it is like with the car, for instance. Once you buy a car the one responsible for the maintenance is the owner. I think it is for us paying attention to because sometimes the maintenance is very expensive and spare parts are difficult to obtain. There are a lot of problems which can occur, for example the question if spare parts have to be from the original manufacturer or if they can be from another manufacturer. That is a specific problem and WHO published a report on that, on health technology management.

**Question Eric:**

***Do you know about the development of medical devices for feminine hygiene, such as products for menstruation?***

**Answer by Josée:**

No, not specifically.

