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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Inter-American Development Bank

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Josée HANSEN
Consultor Red CRITERIA del BID
20 Junio 2019

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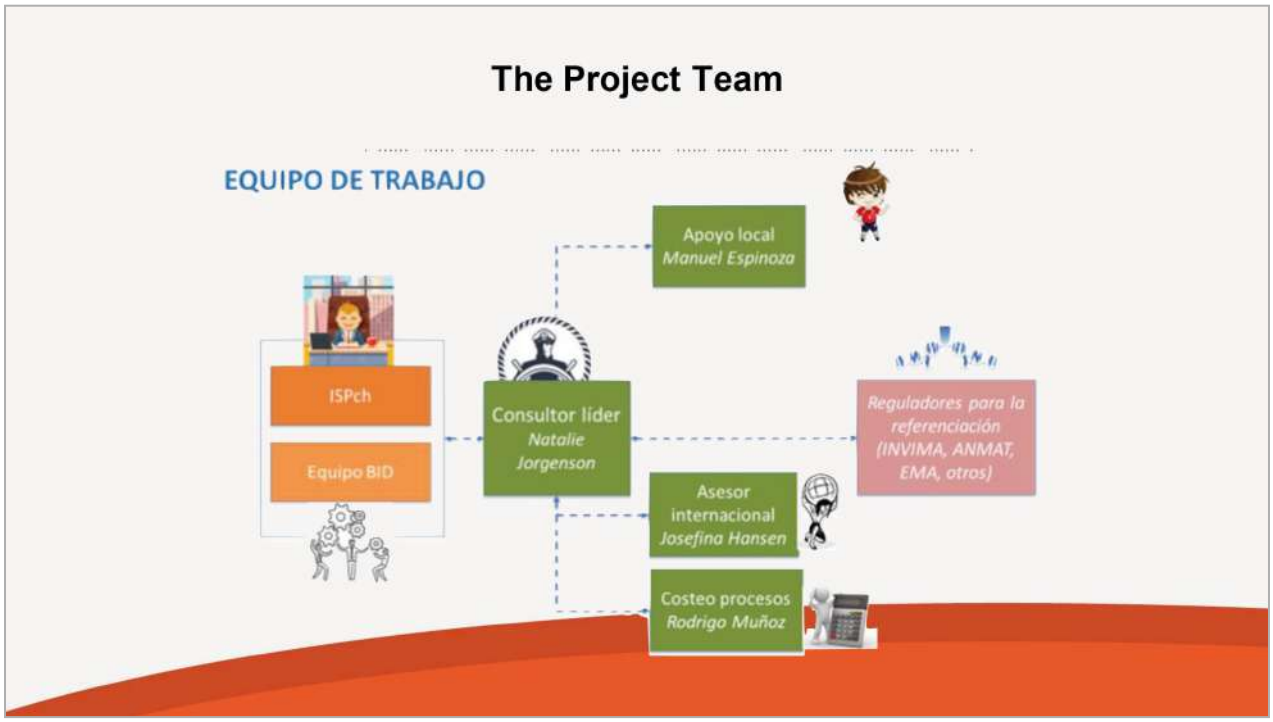
IADB Project

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

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

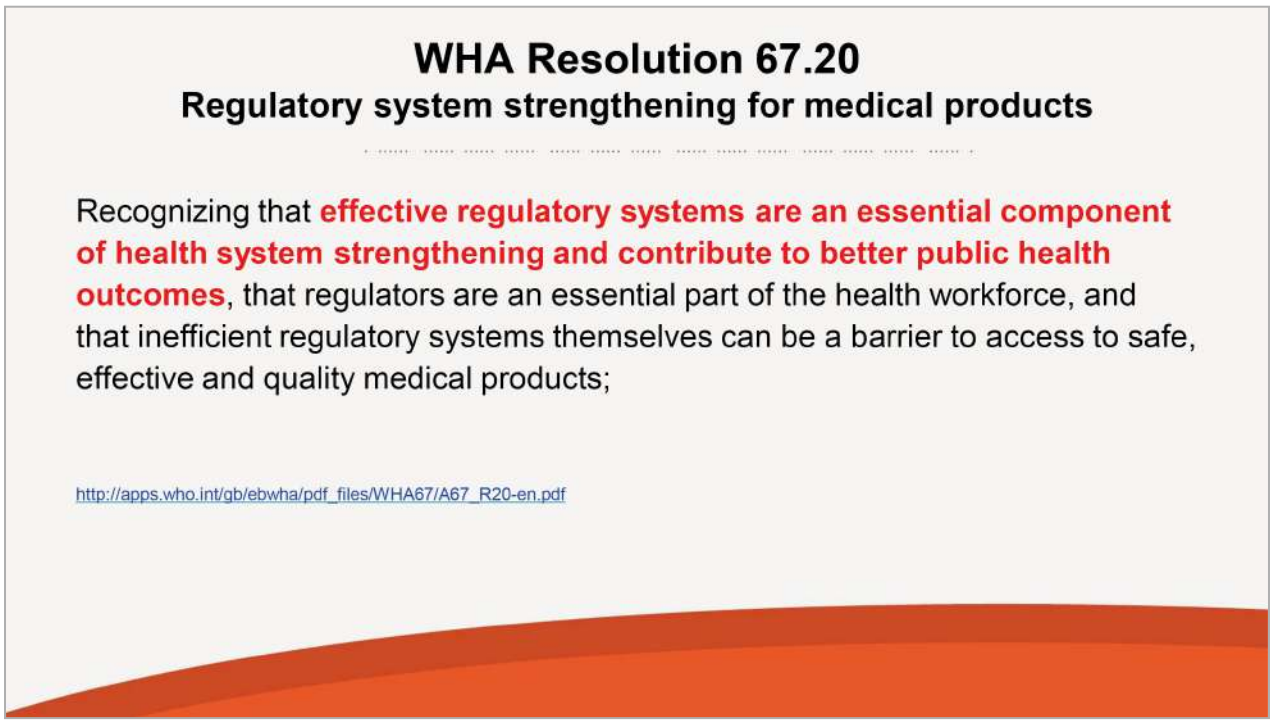
Minute 00:05:34

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 Jorgensan. She is from Argentina. There are two national consultants and I am the international consultant in this team.

CONTENTS

Minute 00:05:55

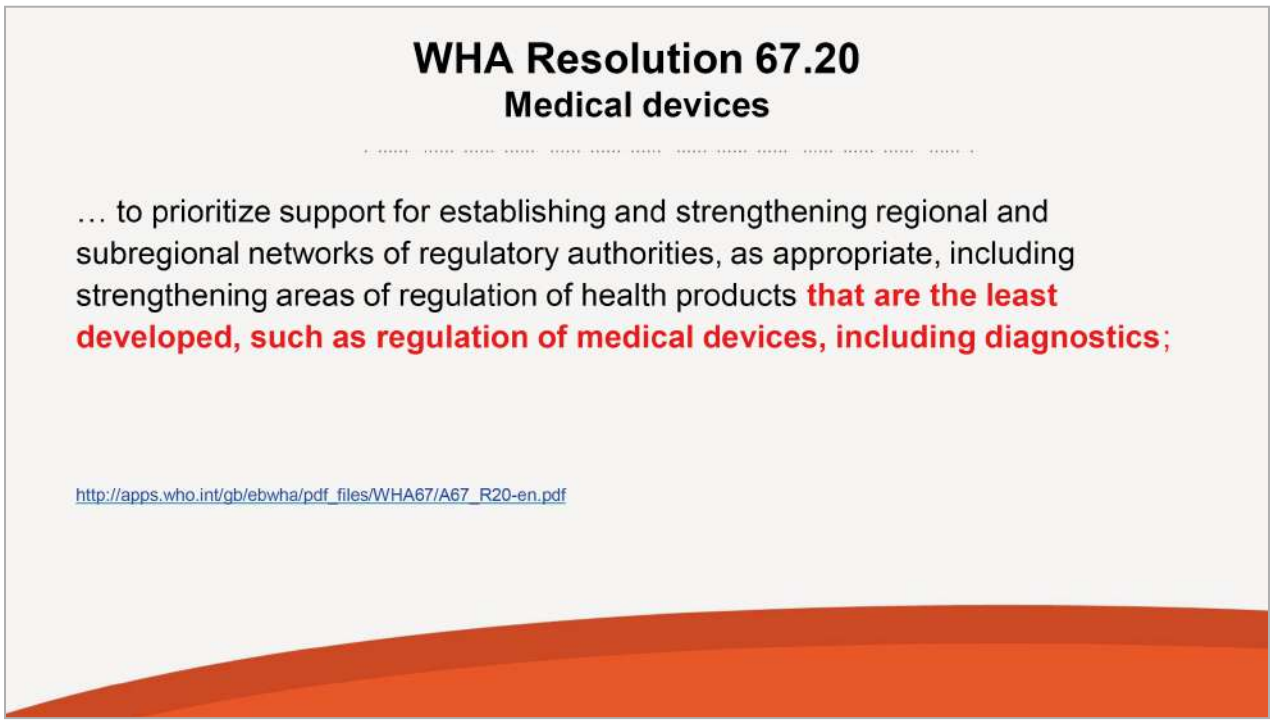
I will guide you through the presentation by touching upon the following topics. What are medical devices? Why do we need to regulate medical devices? And how are we going to effectively and efficiently regulate medical devices? Then we will look at when to start regulating medical devices. I will also 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

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

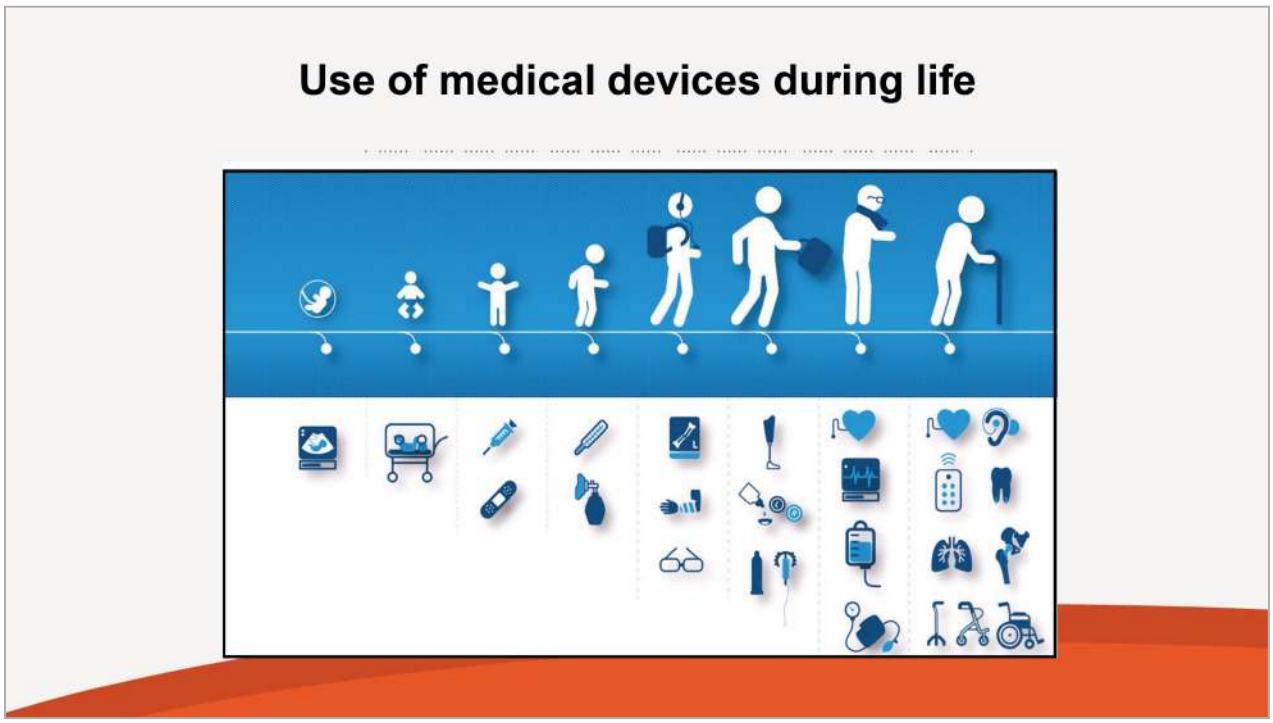
Minute 00:07:06

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

Minute 00:07:24

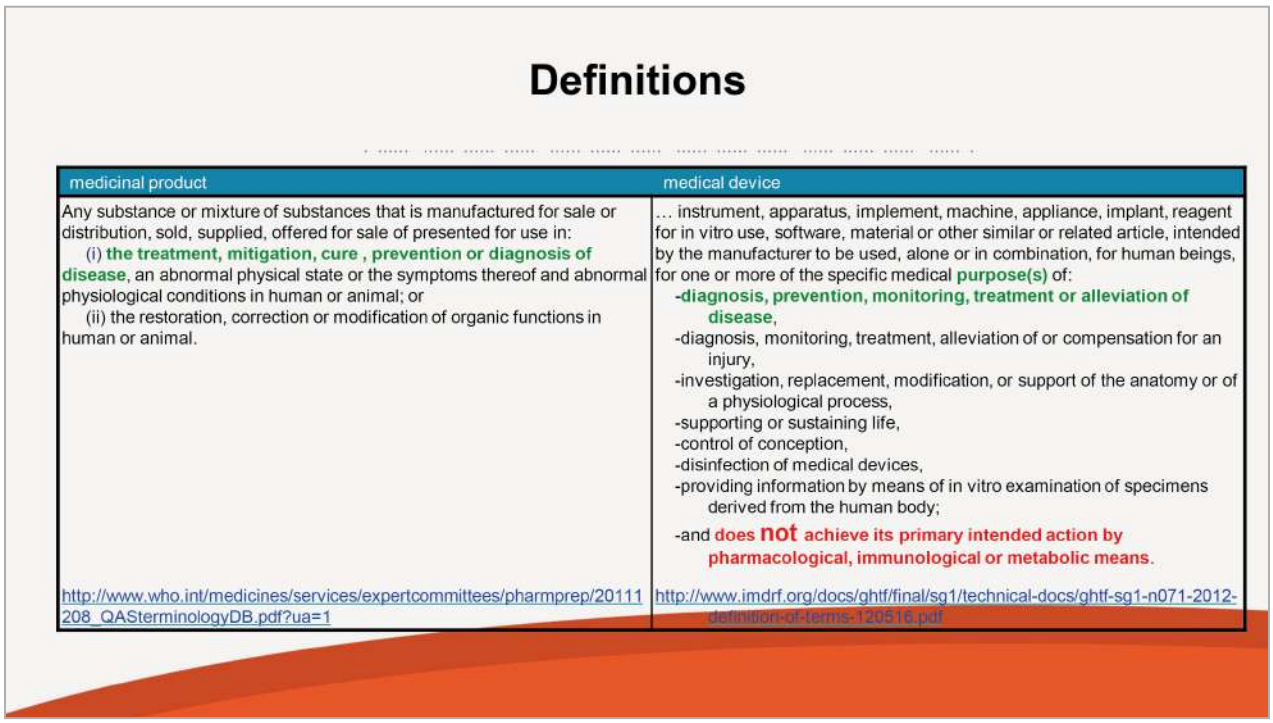
So what are we talking about? What are medical devices? Well it is a huge group of products of very different kinds, from a wheel chair, even a walking stick to a hip implant, a diagnostic device, surgical gloves, contraceptives, surgical equipment, CT scans, MRI scan equipment, you name it. There are 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

Minute 00:08:58

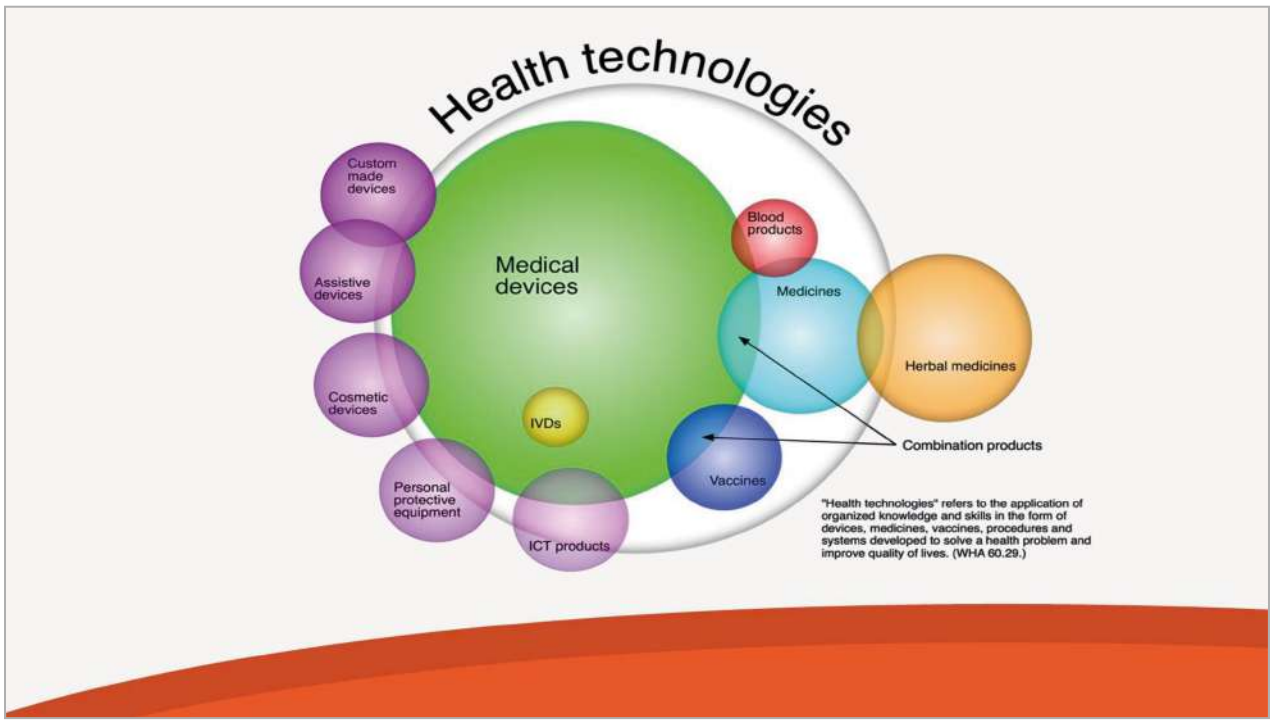
This is a picture of the phases of a human life, from before birth until very old. Medical devices are being used in every phase of a person's life. Before birth in monitoring pregnancy and until the last phase of life where a person needs a walking stick a hip implement, a hearing aid, dental implants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



DEFINITIONS

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.

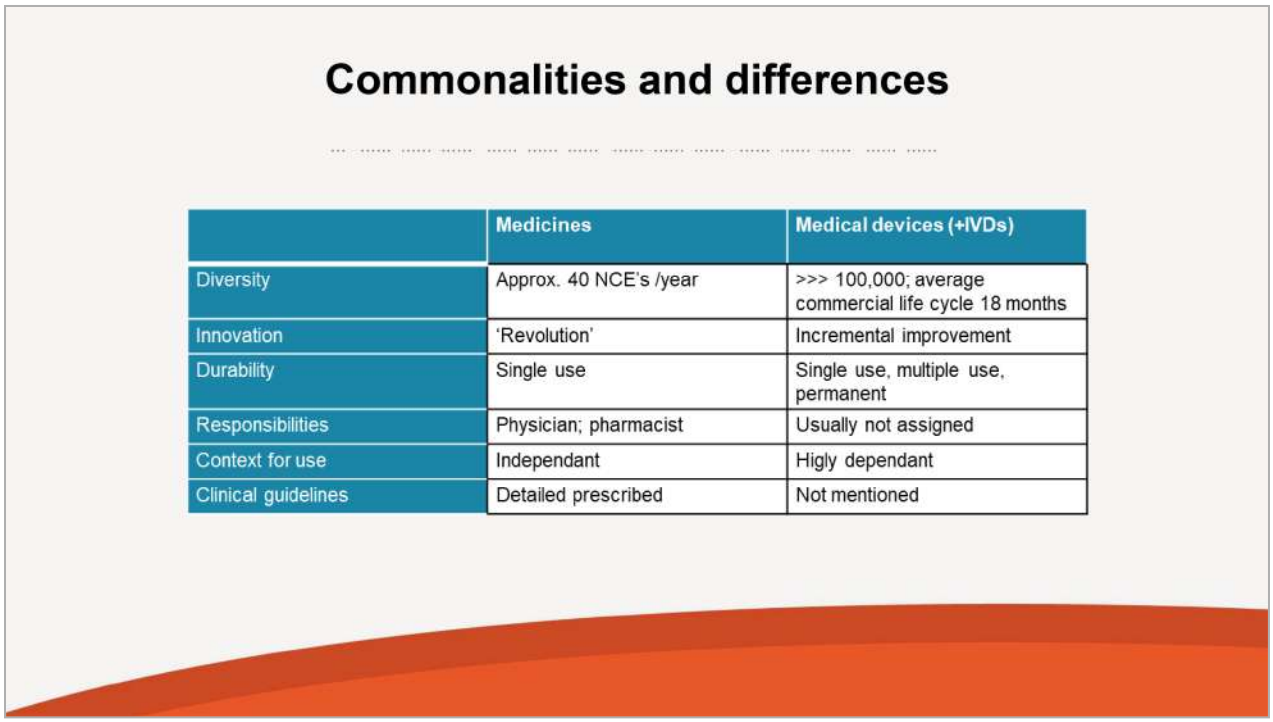


HEALTH TECHNOLOGIES

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.

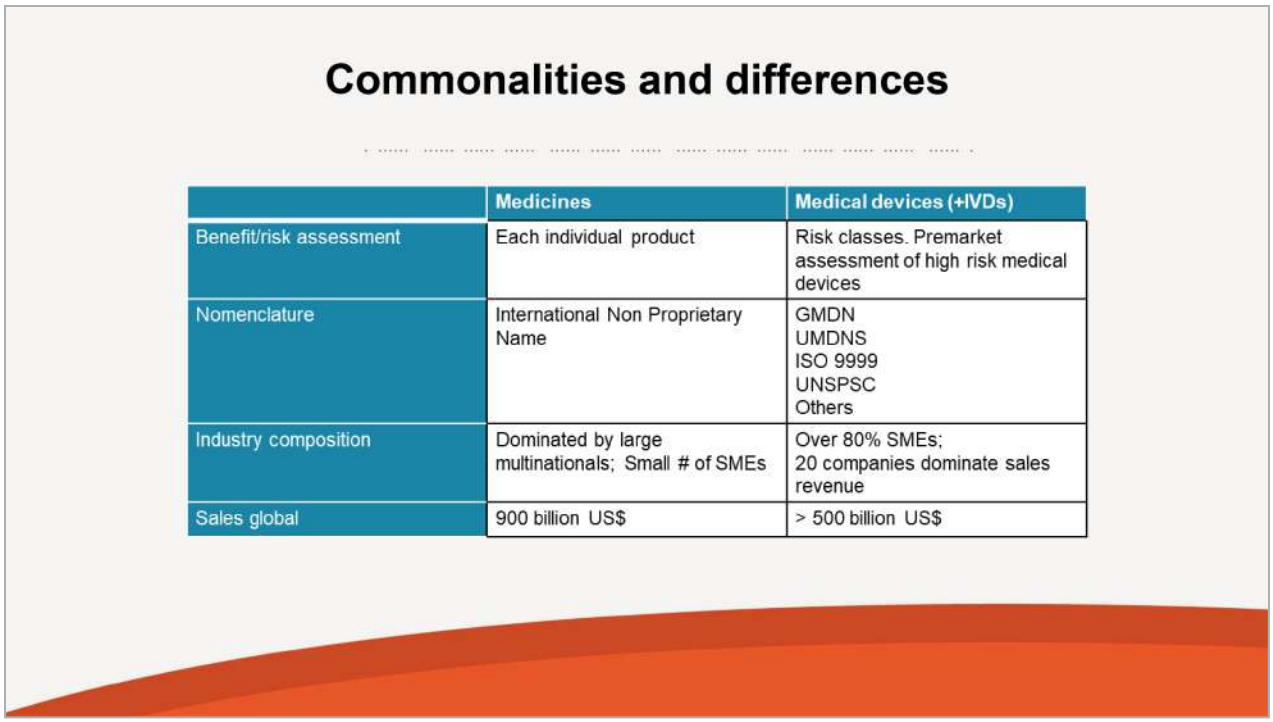


COMMONALITIES AND DIFFERENCES

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.



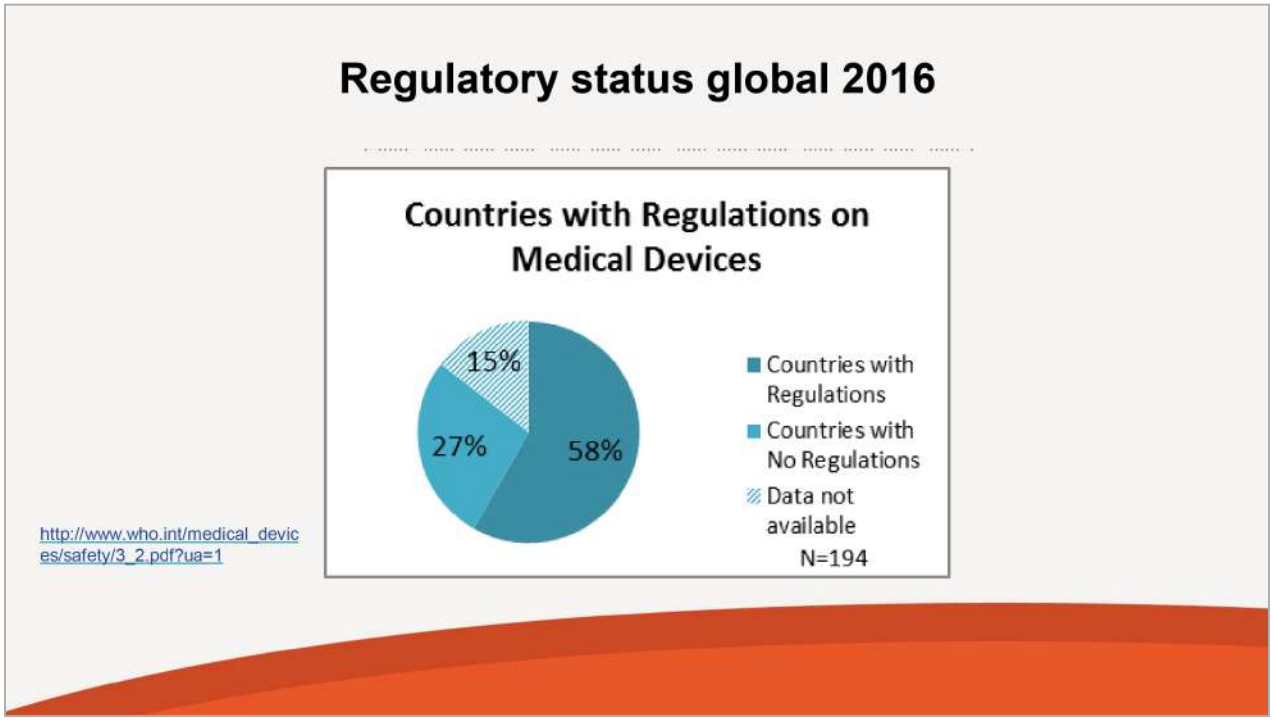
COMMONALITIES AND DIFFERENCES

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

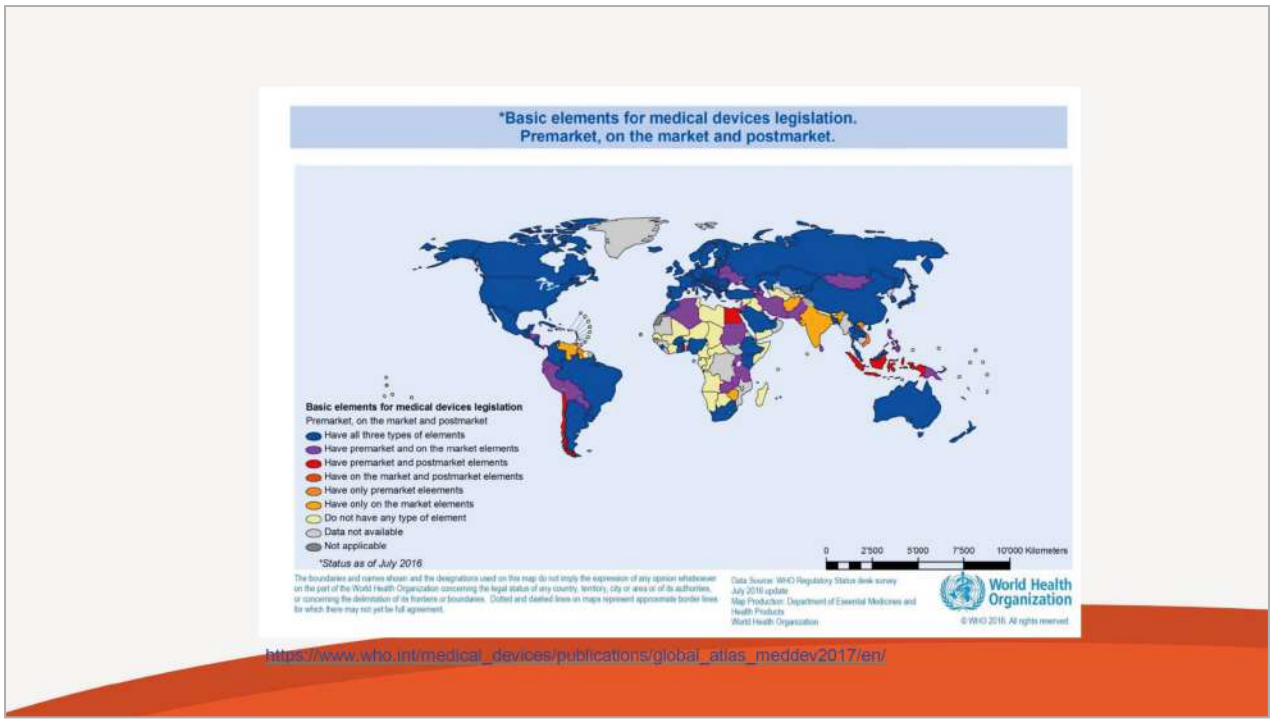
in case of a problem. There is a tendency towards GMDN but it has not been accepted world wide as the unique nomenclature system for medical devices.



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…

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.

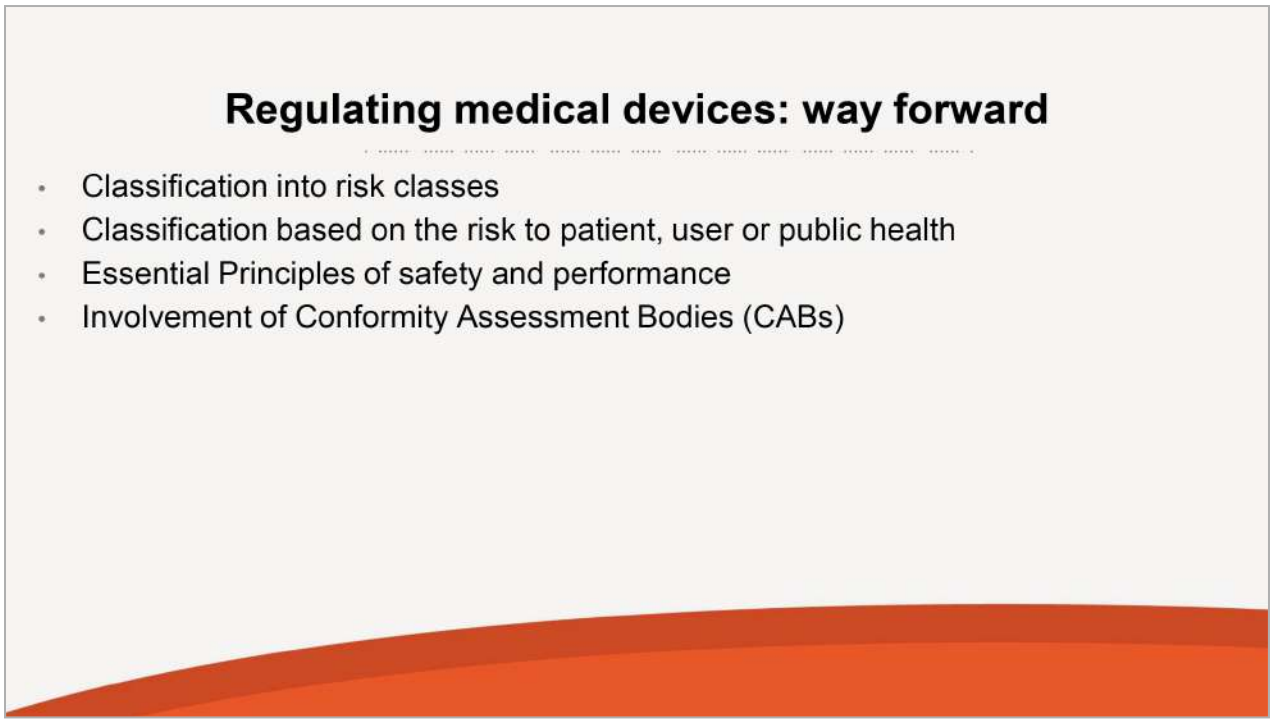
A level playing field is also important because if there is no level playing field the bad guys benefit from the fact that there is no regulation and the good guys suffer from the bad guys in that regard.

REGULATING MEDICAL DEVICES - CHALLENGES

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.

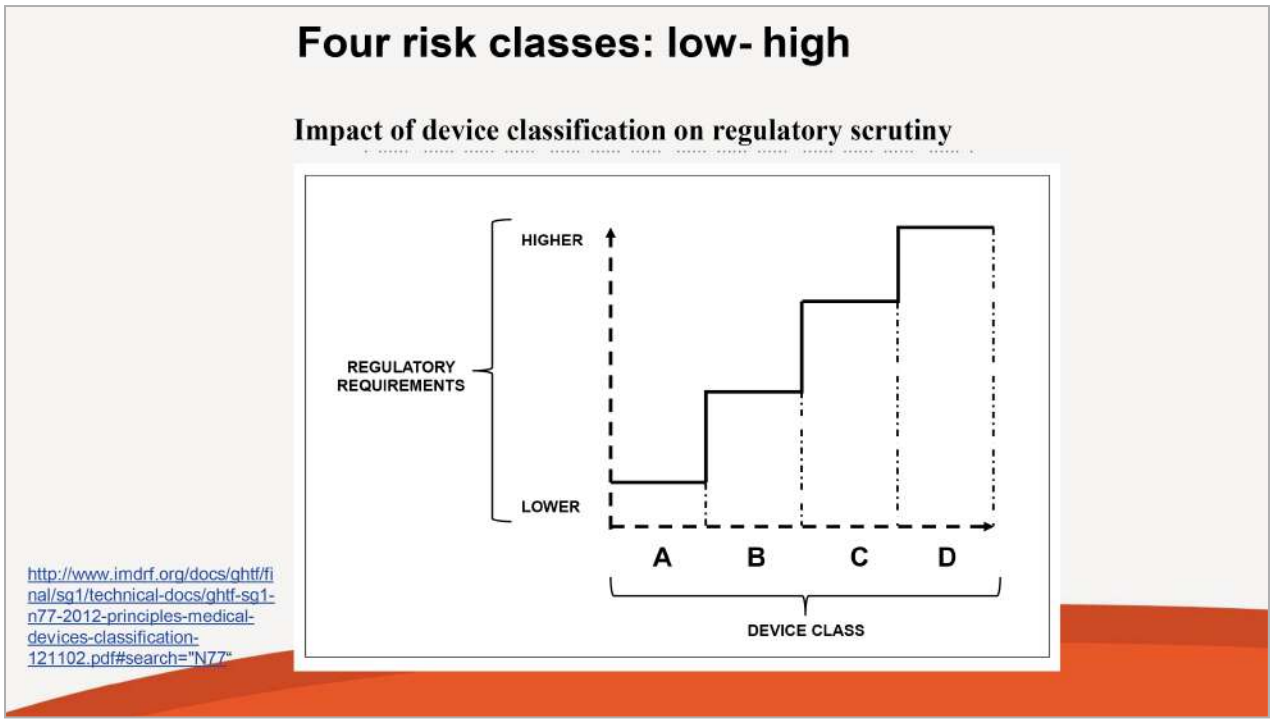
The number and the characteristics of medical devices is of course a challenge. When countries starts regulating medical devices there are already tens of thousands, or even more, products on the market. How to start regulating when everything is already on the market? Due to the characteristics and 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

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 a 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.

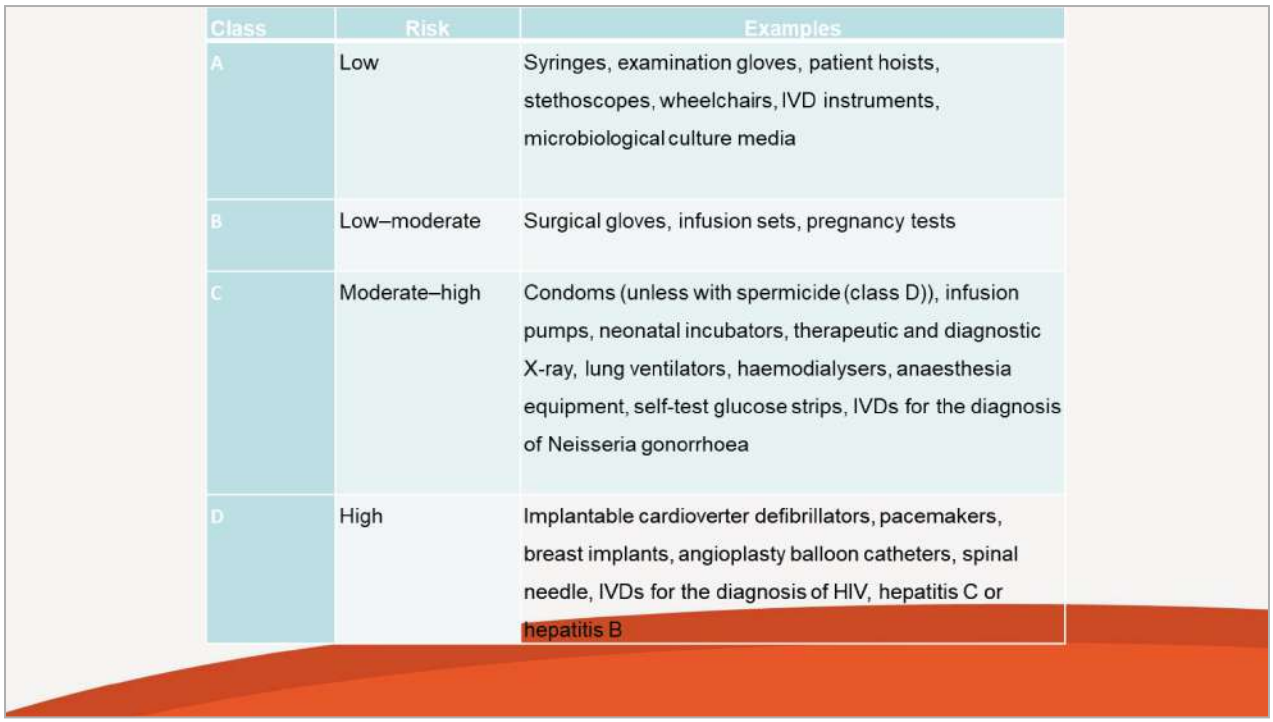


FOUR RISK CLASSES: LOW-HIGH

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.

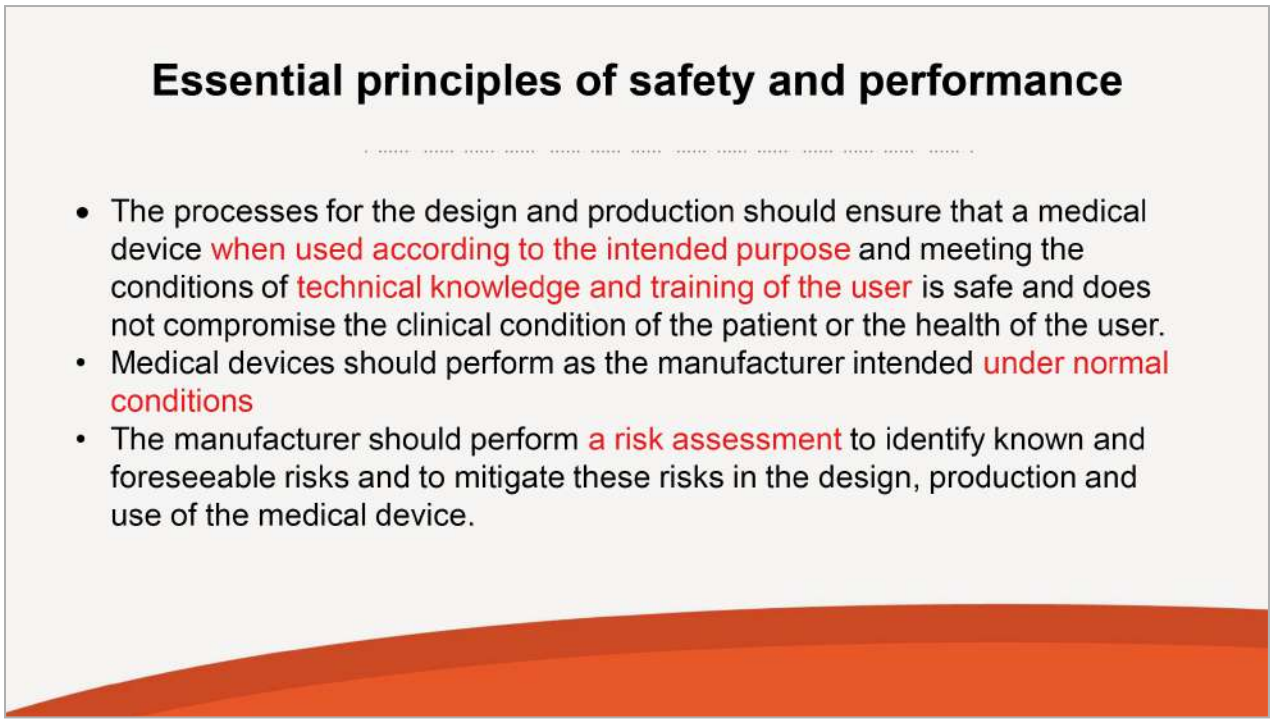


Class	Risk	Examples
A	Low	Syringes, examination gloves, patient hoists, stethoscopes, wheelchairs, IVD instruments, microbiological culture media
B	Low–moderate	Surgical gloves, infusion sets, pregnancy tests
C	Moderate–high	Condoms (unless with spermicide (class D)), infusion pumps, neonatal incubators, 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

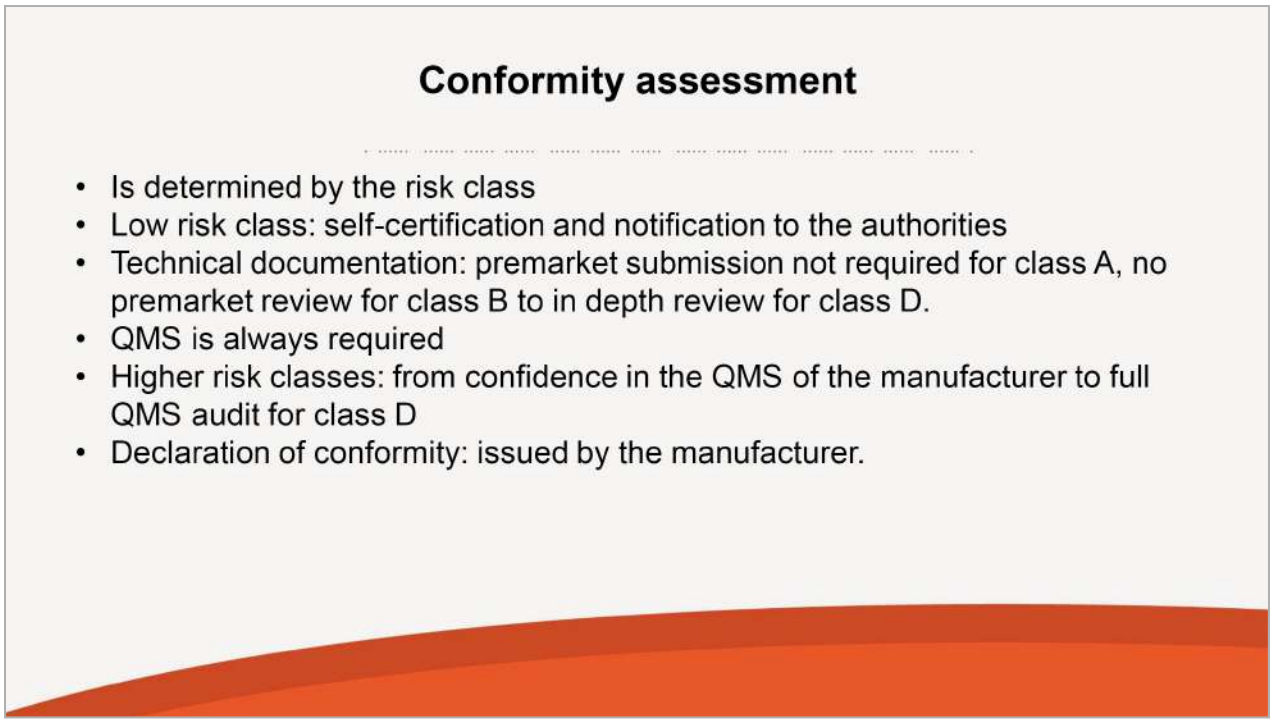
These are just some examples of low and high-risk devices. Low-risk devices are, for example, syringes or IVD instruments. On the other hand the tests for some diseases that cannot be cured, are high-risk devices. Condoms, for example, are classified as moderate risk but with spermicide then they are 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

Minute 00:22:17

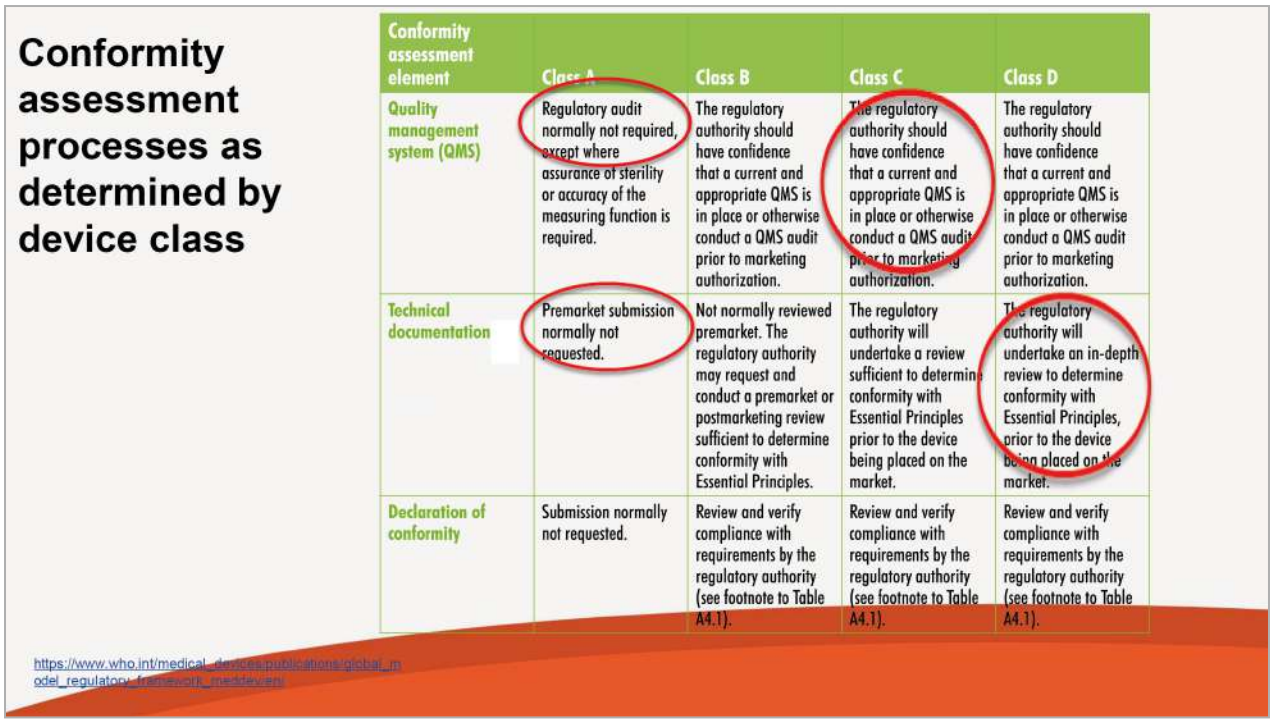
This slide is related to the essential principles. All medical devices should comply with the essential principles of safety and performance. The essential principles, in fact, include the design and the process of a medical device. When a medical device is used under normal conditions and according 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

Minute 00:23:31

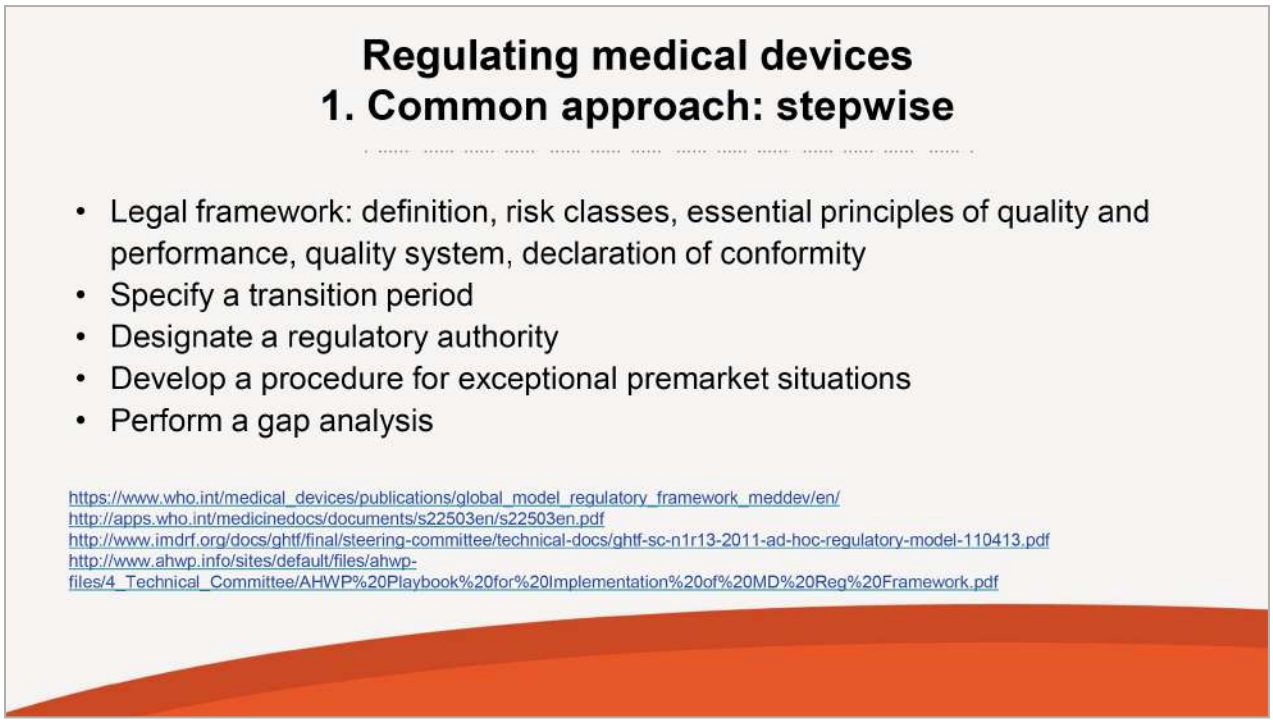
So the manufacturer is responsible for compliance but the authority is going to assess the medical device to check if what has been stated by the manufacturer is really true. However, this is not the case for the low risk devices, only for high-risk devices. The involvement of the regulator is higher 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

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

Minute 00:25:24

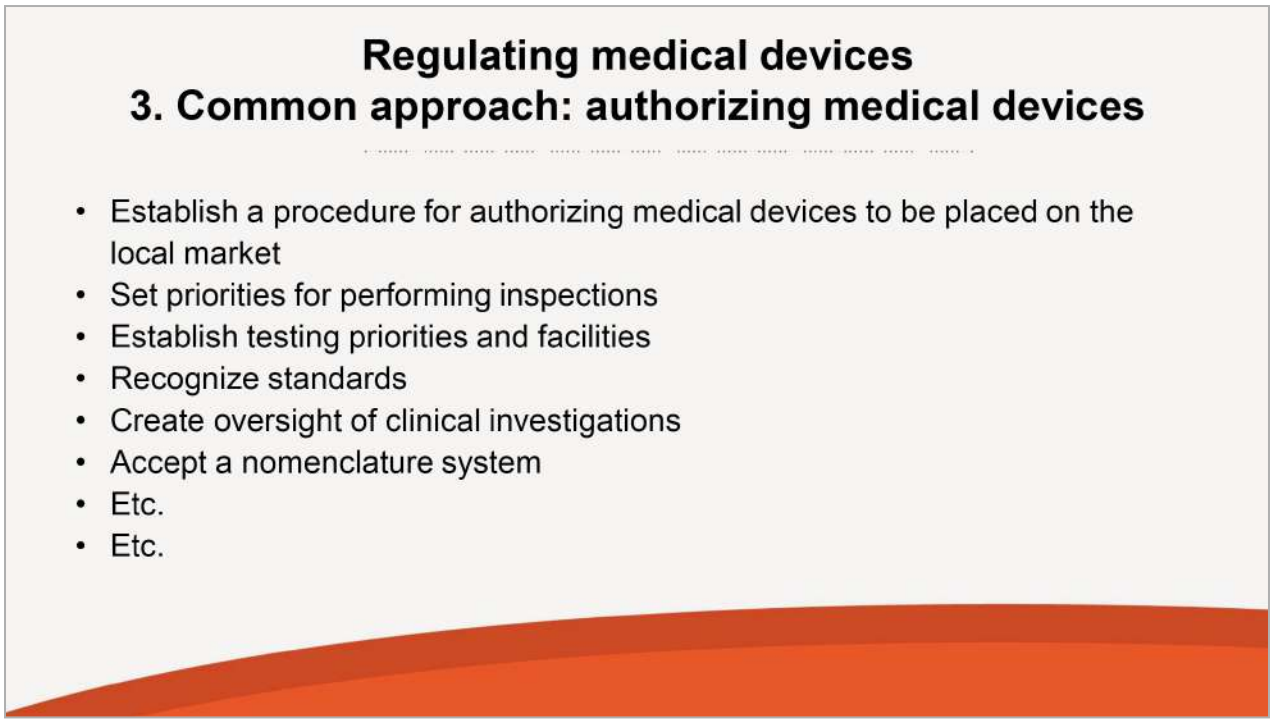
Those are the principles, but how to start in a country where there is no regulatory system in place? There is a common approach by a number of international bodies, like WHO and the Asian Harmonization Working Party.

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

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

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.

ENABLING CONDITIONS FOR REGULATING

Minute 00:29:07

On how to regulate effectively, the OECD developed a set of guidelines, the so called "Good Regulatory Practices guidelines". Good regulatory practices are internationally recognized processes, systems, tools and methods for improving the quality of regulations. The first set of good regulatory practices was published in 1992 already. In 2012 they published a set of 12 new recommendations.

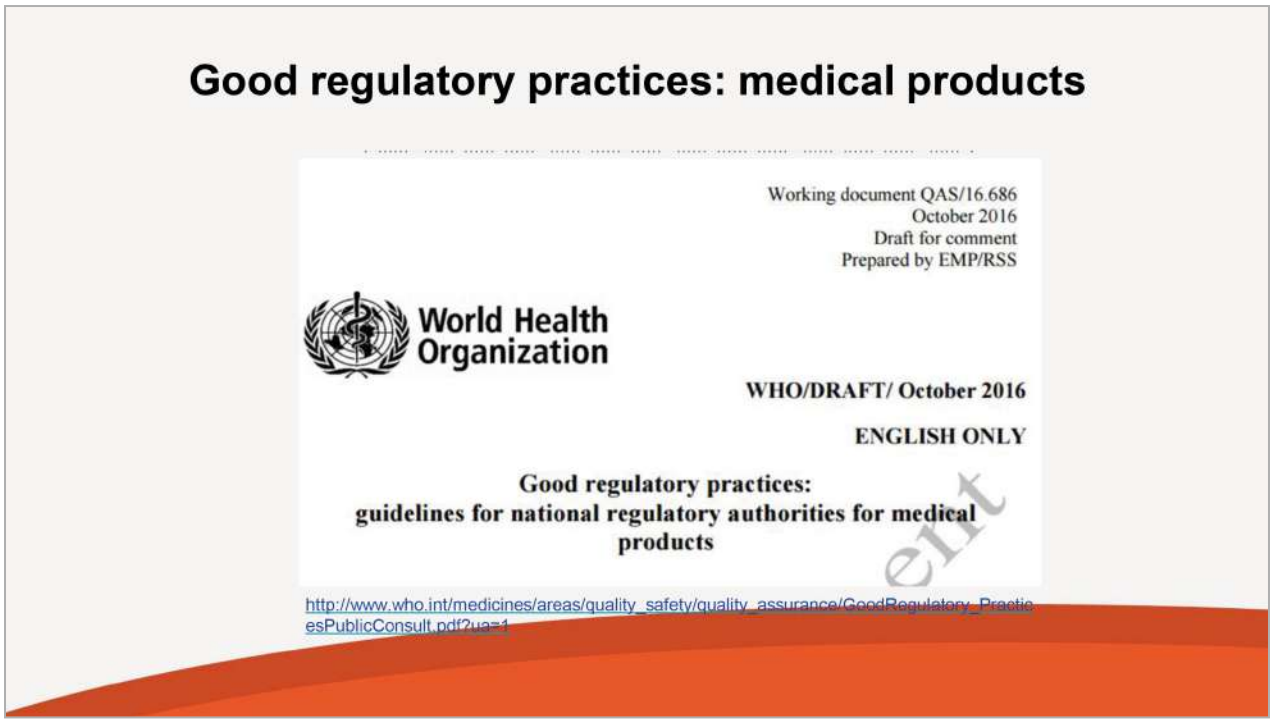
ENABLING CONDITIONS FOR REGULATING

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.

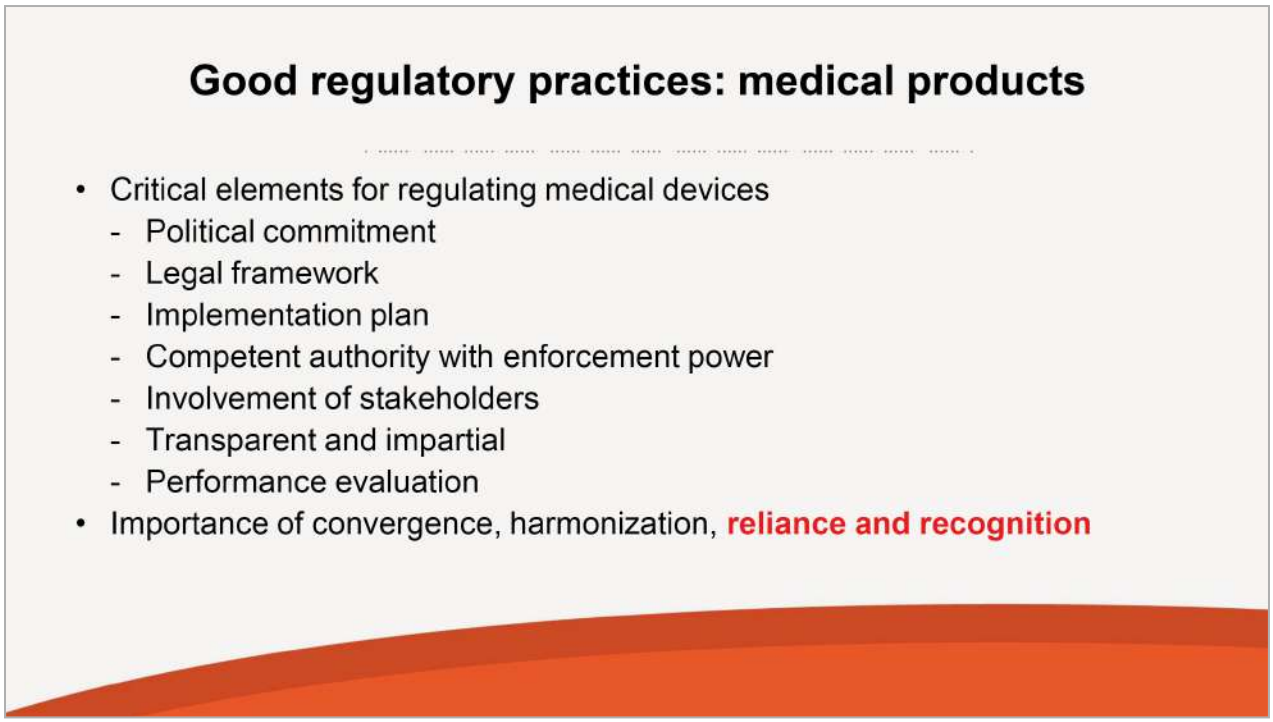
The number 12 on this chart is about international harmonization. In a global market like to medical devices market sticking to international standards is efficient and effective and makes life easier for everyone.



GOOD REGULATORY PRACTICES: MEDICAL PRODUCTS

Minute 00:31:22

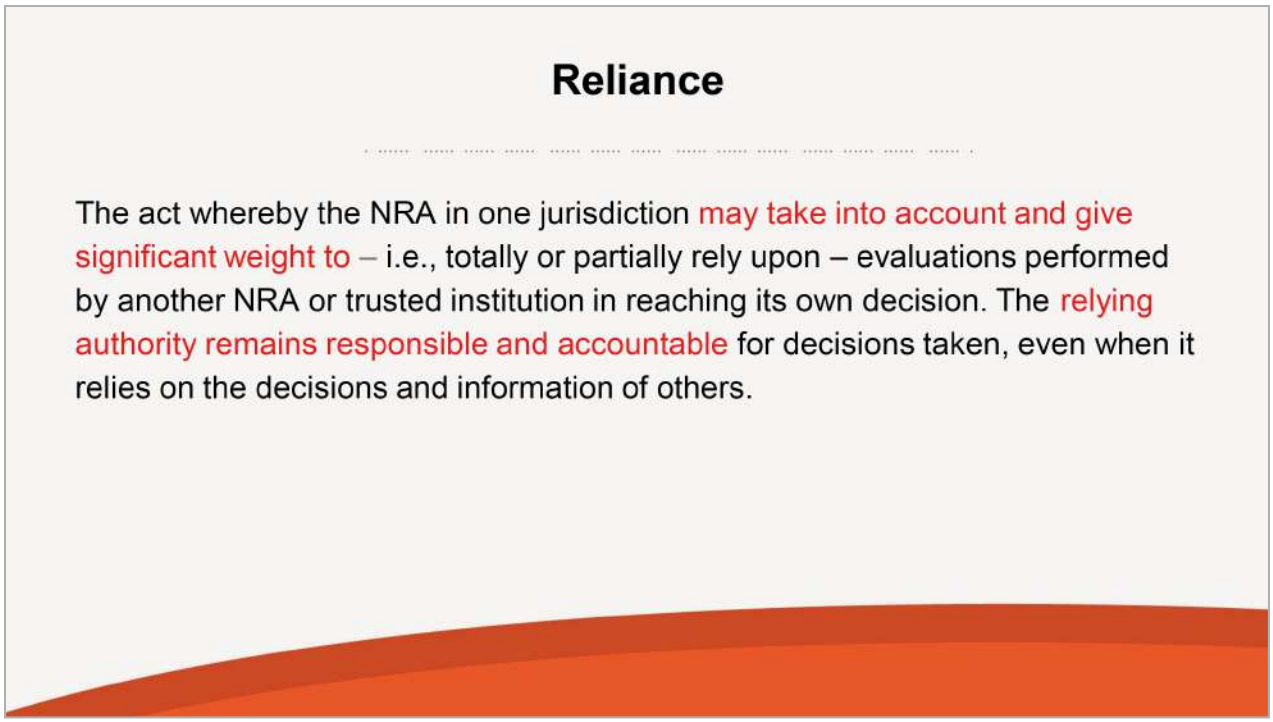
WHO, based on the OECD guidelines, developed good regulatory practices focused on medical products. It is still a draft but I think it is a good document.



GOOD REGULATORY PRACTICES: MEDICAL PRODUCTS

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

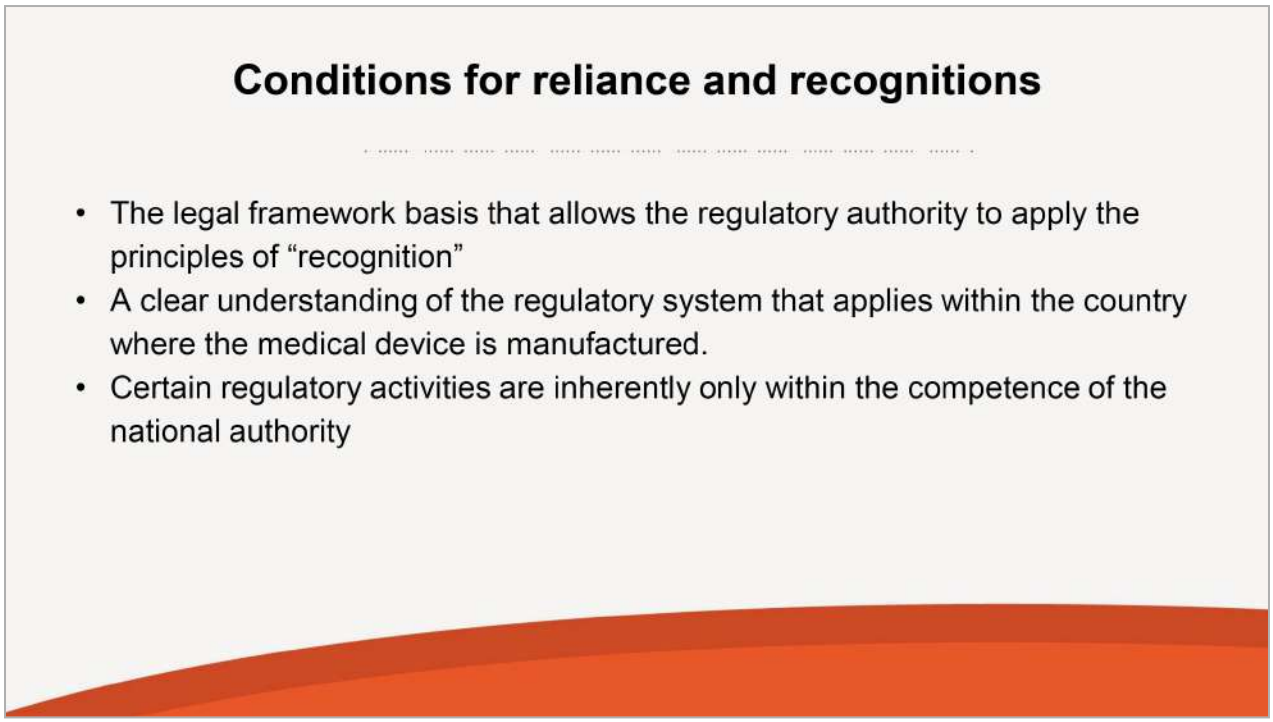
Minute 00:32:30

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

RECOGNITION

Minute 00:32:50

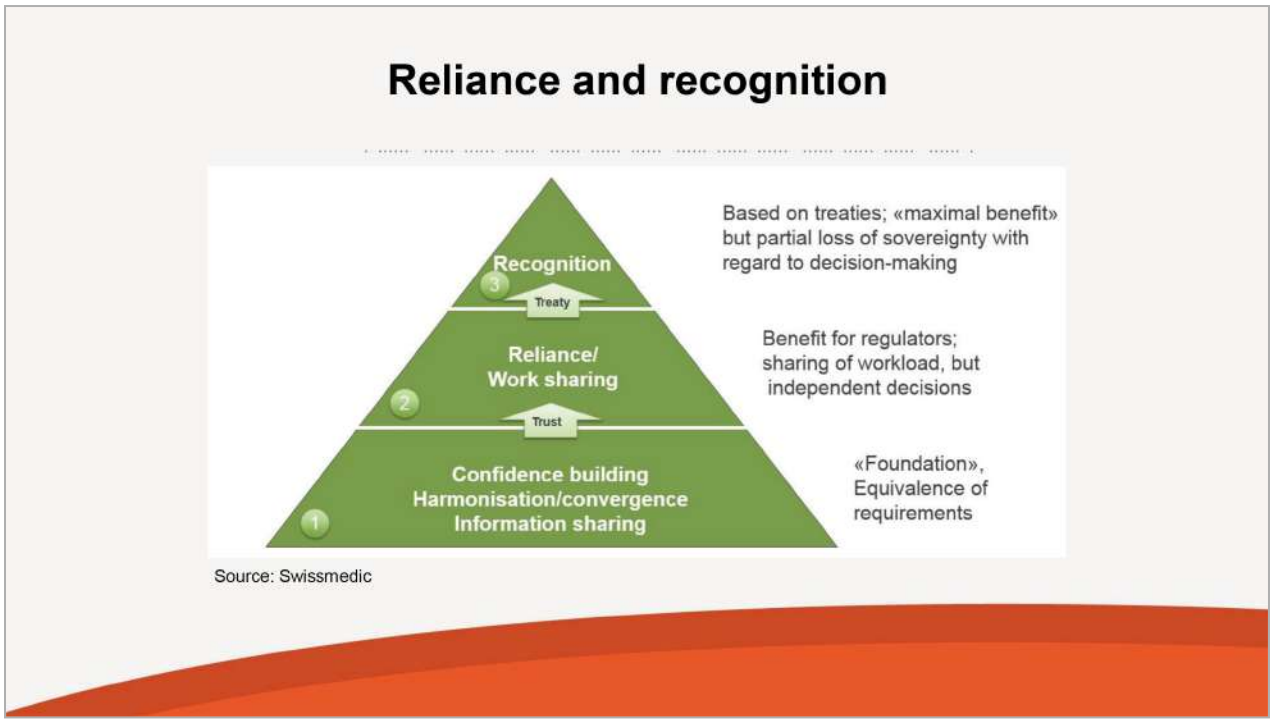
Recognition, on the other hand, goes one step further. It is the routine acceptance of the regulatory decision of another jurisdiction. There are recognition agreements between mature authorities, like the EU and Switzerland, for instance. For medical devices there is a complete open market between Switzerland 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 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

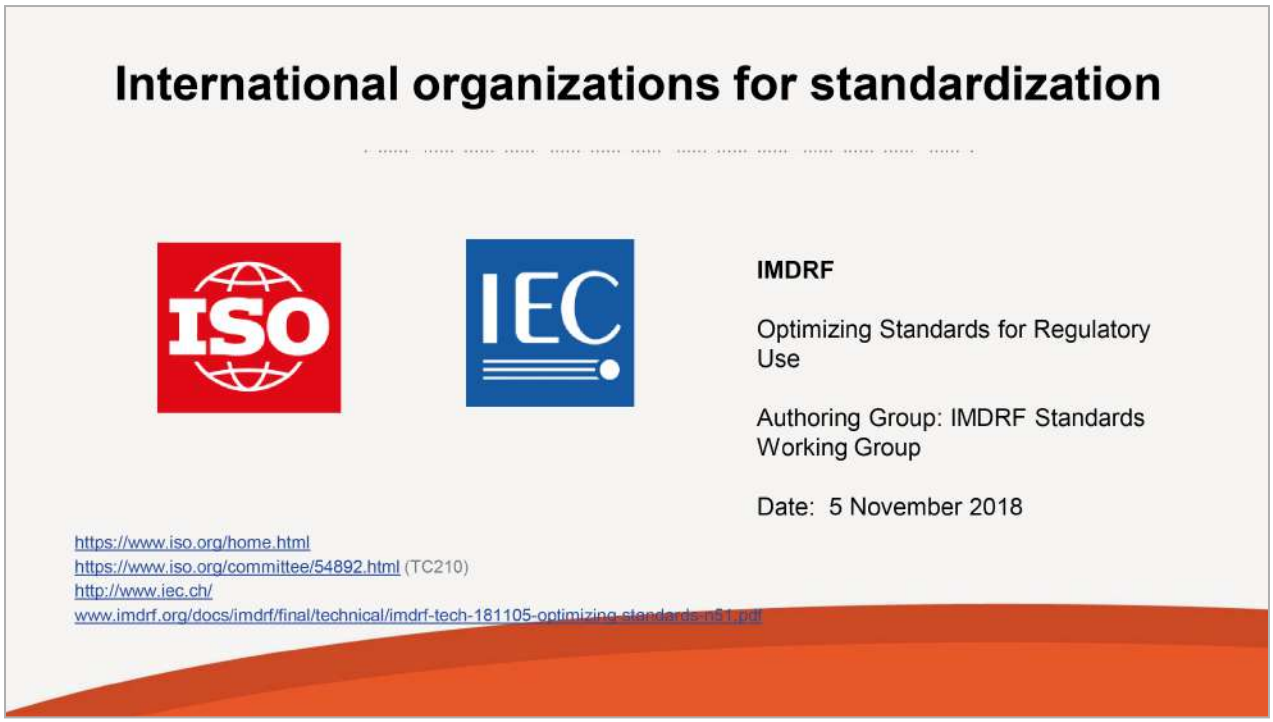
Minute 00:35:15

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

Minute 00:35:55

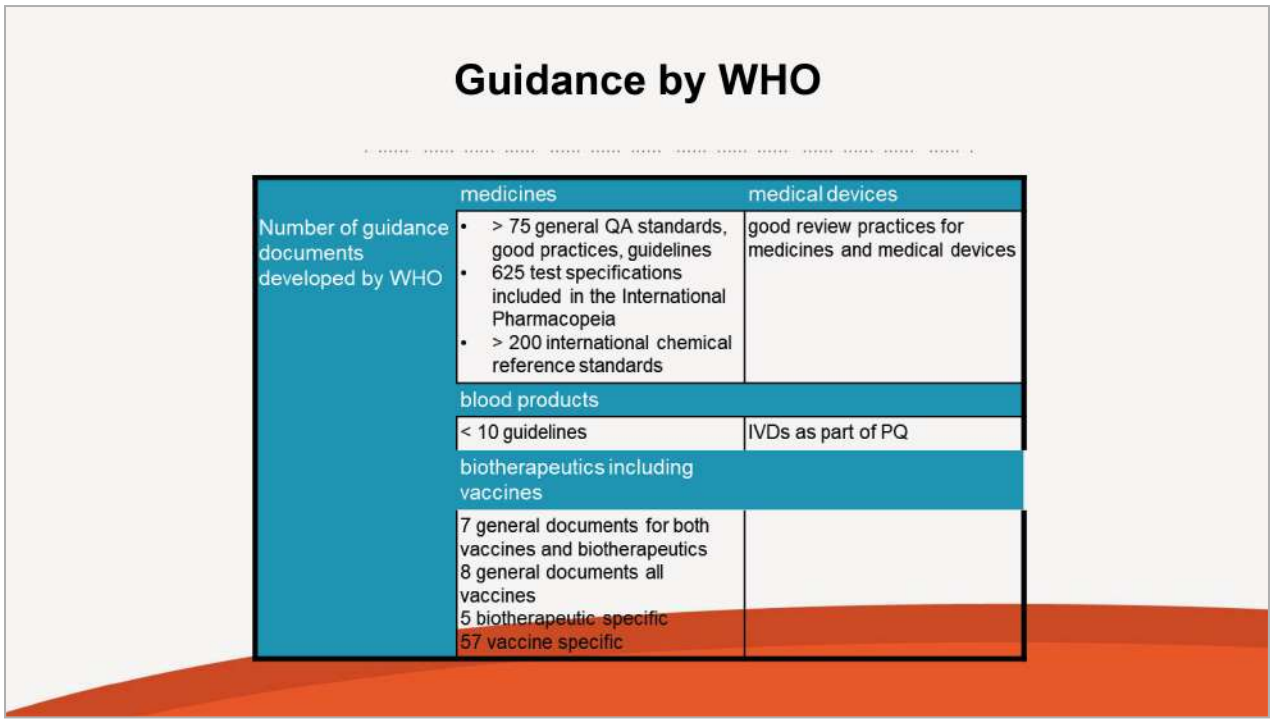
I have mentioned the importance of aligning with international standards. Therefore, I will show you some slides on international harmonizing bodies. I think the most important is the International Medical Device Regulators Forum. The IMDRF is important in developing harmonized guidelines. It started 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

Minute 00:36:55

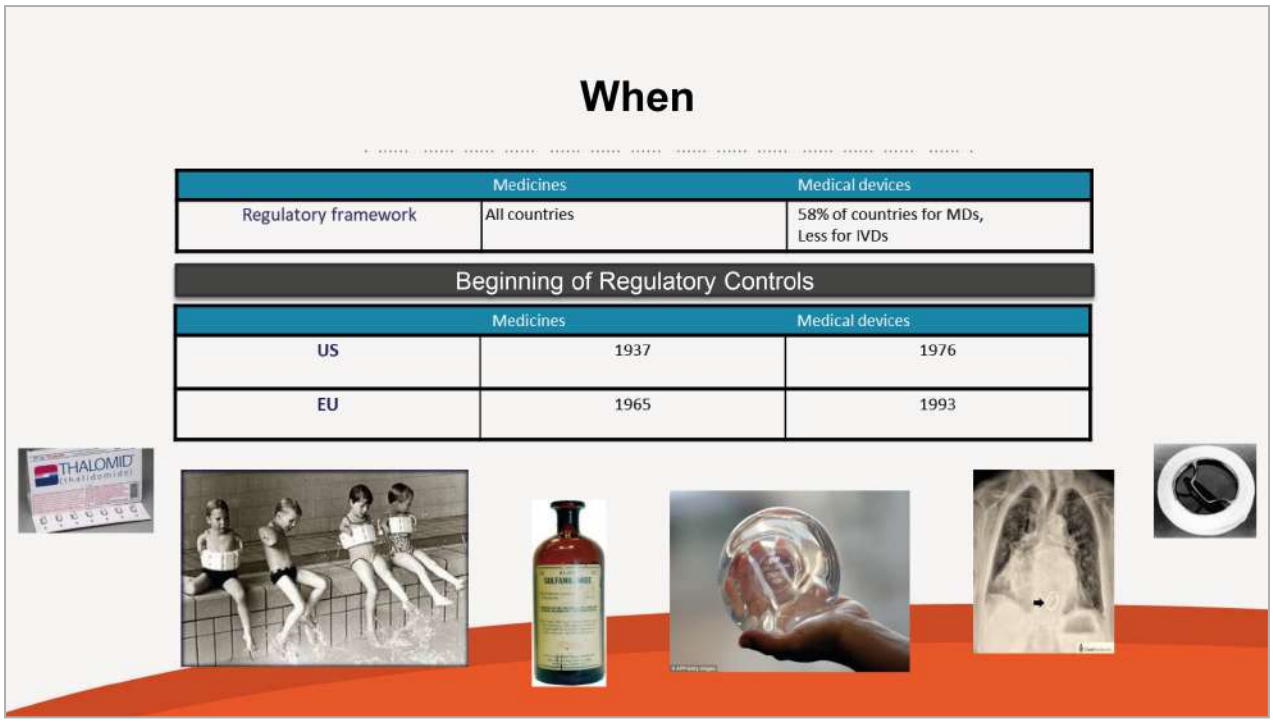
Unlike medicines, where regulatory authorities develop standards, for medical devices ISO and the International Electro-technical Committee (IEC) are important bodies for the development of standards. Currently IMDRF is taking part in developing the standards. Unfortunately the standards from ISO and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



GUIDANCE BY WHO

Minute 00:37:32

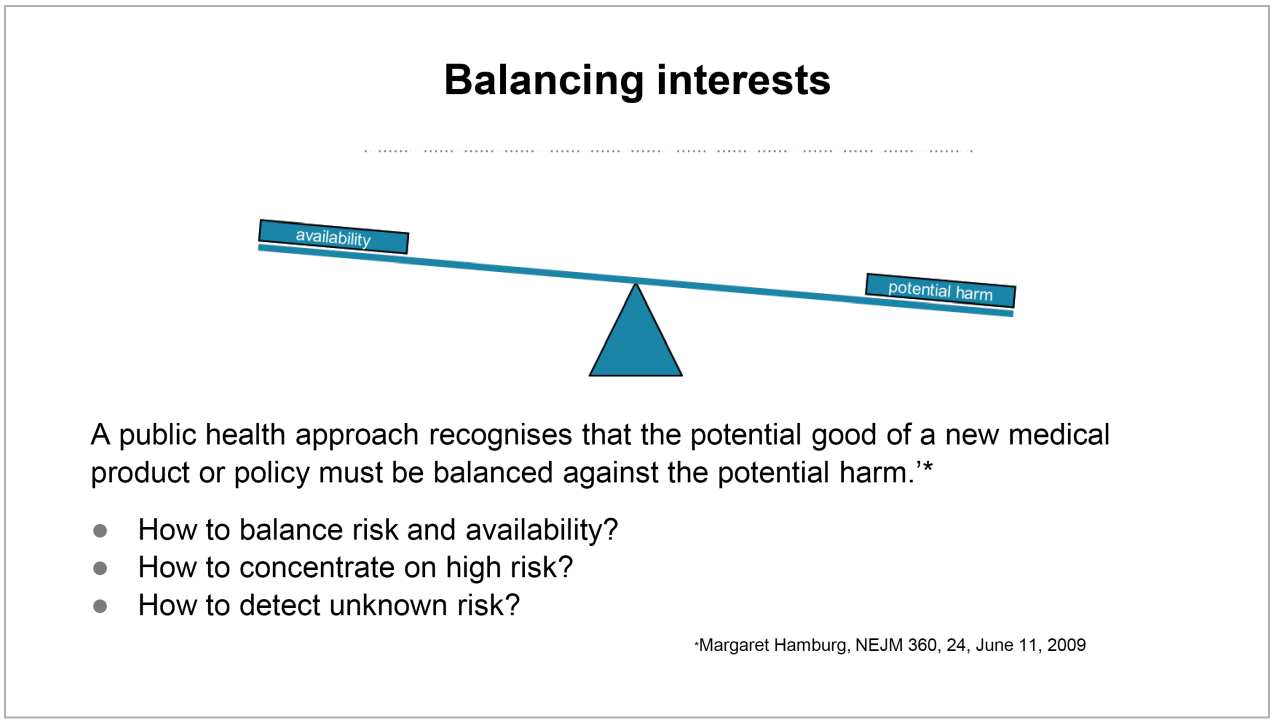
WHO developed a limited number of standards for medical devices and they are all part of the pre-qualification program and focus on IVD diagnostics.



WHEN

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

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

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

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

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

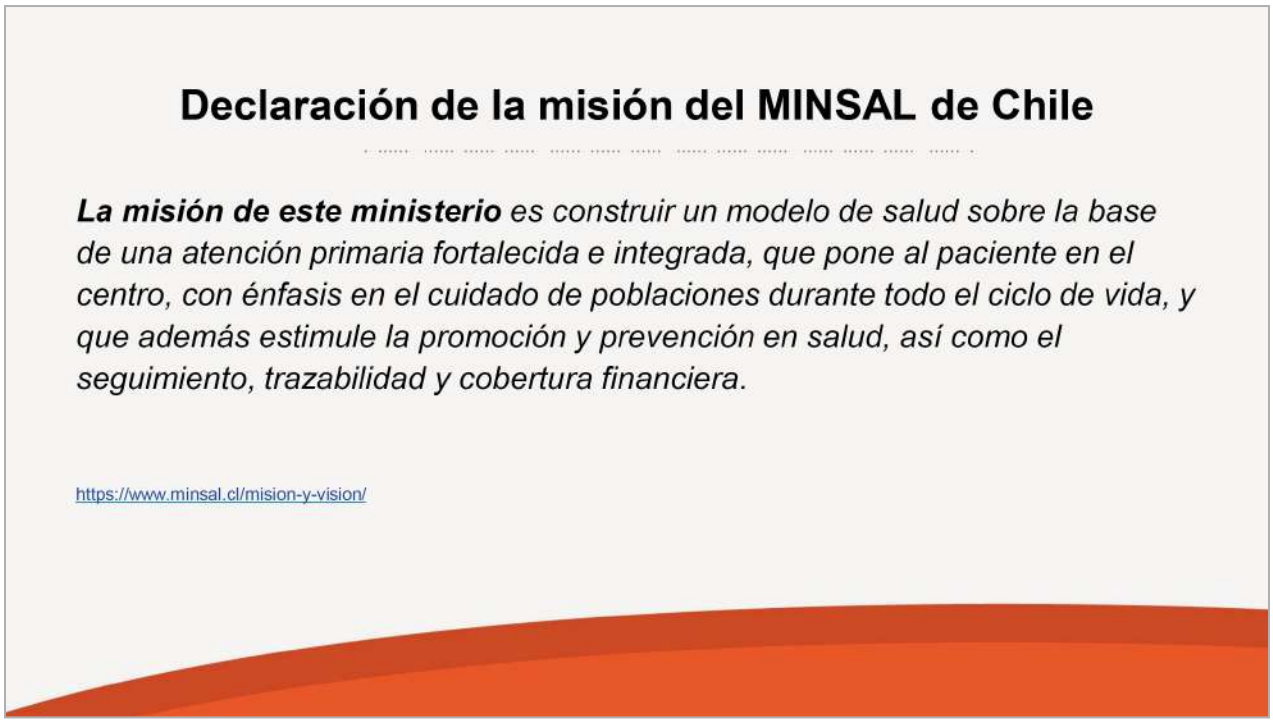
Minute 00:43:03

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

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

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

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.

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

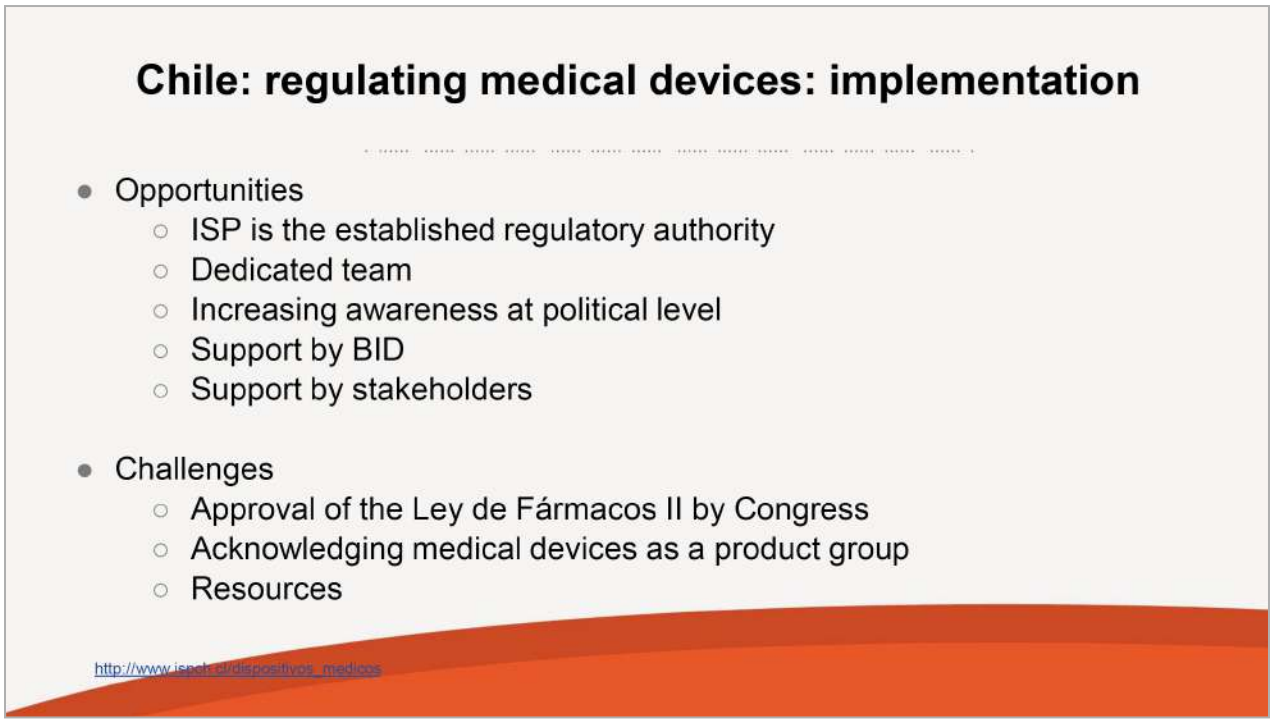
Minute 00:45:15

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.

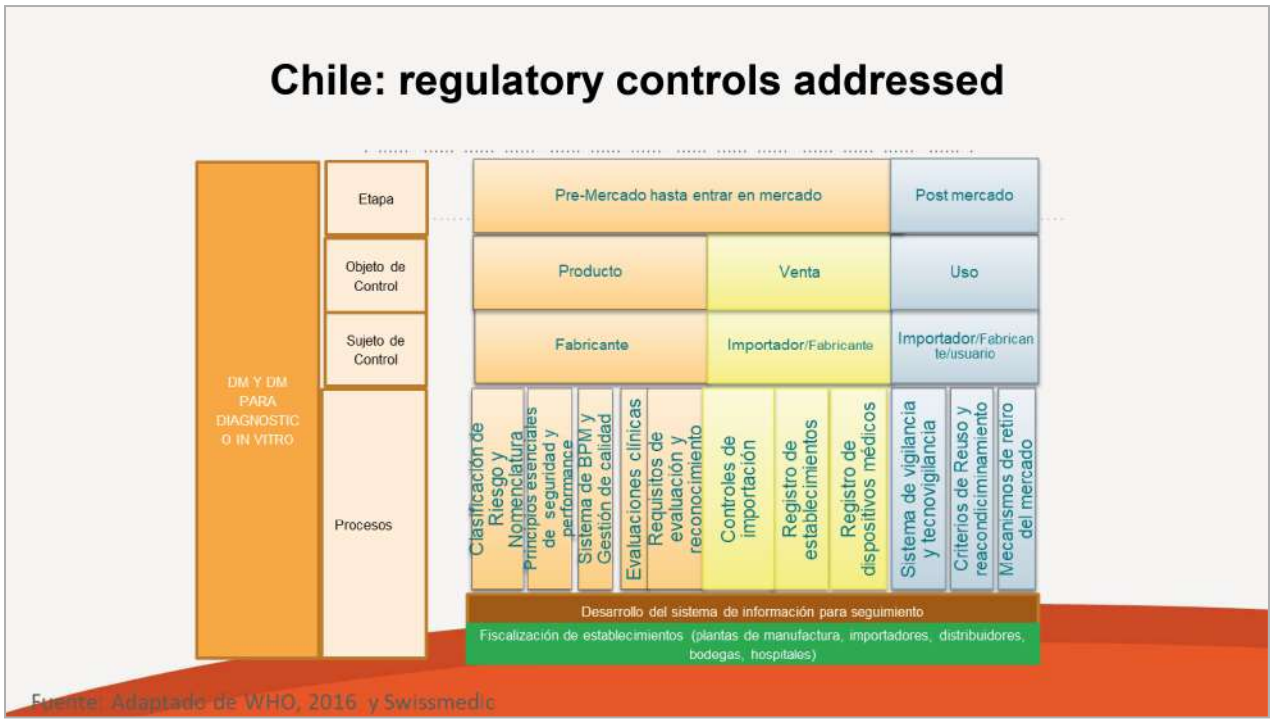


CHILE: REGULATING MEDICAL DEVICES

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?

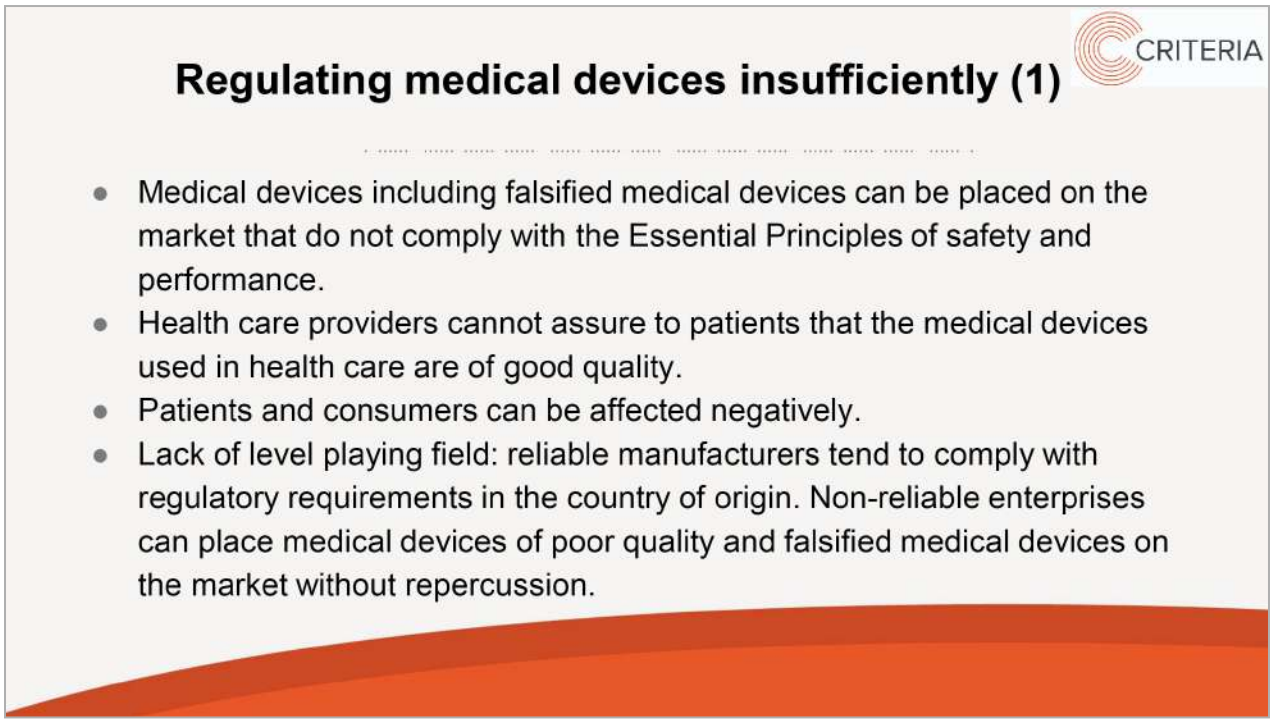


CHILE: REGULATORY CONTROLS ADDRESSED

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.

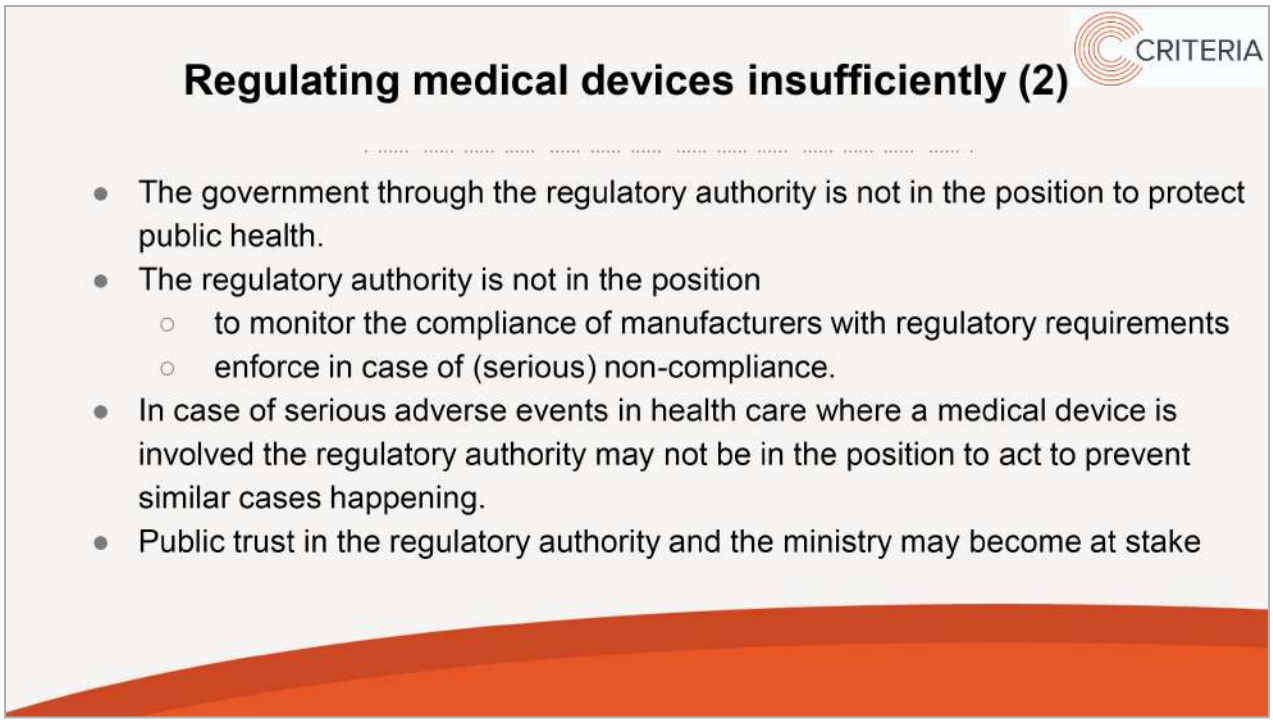
The third row shows the responsible party, which is the manufacturer and importer in the pre-market and then at market entry and in the post market the importer and the user. And the last row shows the regulatory processes. The processes that have been developed include the classification, the principles, 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

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

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

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 needs 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.

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