WEBINAR TRANCRIPTION:

MEDICINES REIMBURSEMENT POLICIES IN EUROPE

Presented by Sabine Vogler. October 24, 2018.

IDB

CRITERIA

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October, 2018

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WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies

PPRI Pharmaceutical Pricing and Reimbursement Information

Gesundheit Österreich GmbH

Medicines Reimbursement Policies in Europe

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IADB Webinar
24 October 2018

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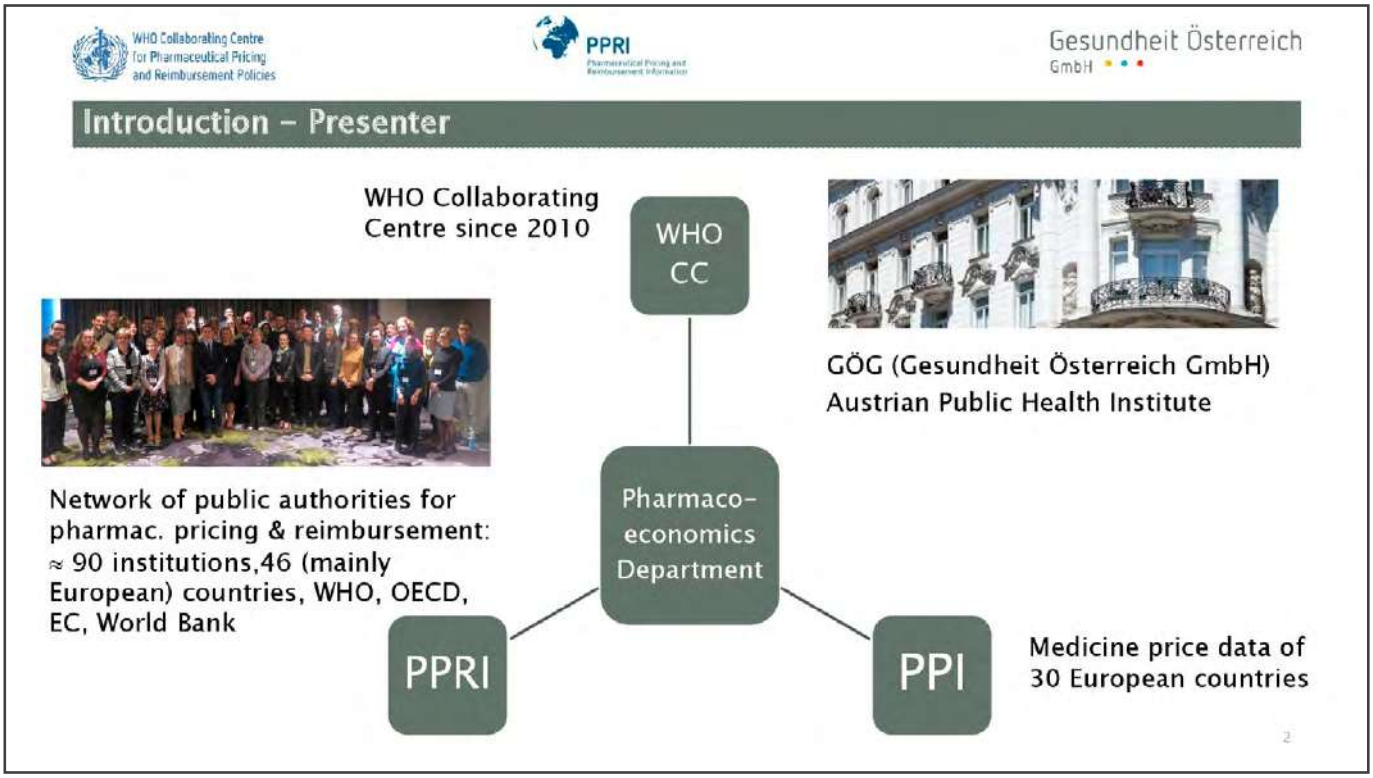


INTRODUCTION

(Min. 00:05:08)

Thank you. You already presented myself so there is no need for me to do so in detail. As you already mentioned I am a researcher working at the Austrian Public Health Institute where I am heading the department of pharmaco-economics. Ursula already mentioned that we work on different areas. She also already explained that we have price data of thirty European countries. That is the PPI service, which is a service that we provide for the Austrian Ministry of Health. When they do the price setting we then check, on a random basis, the price data submitted by manufacturers. It was already also mentioned that we run a network of competent authorities. This is the PPRI network. On the screen you see a photo of our last meeting. We currently have forty-six members, mainly European countries. And it is always good that colleagues have the possibility to share experiences. For the last eight years we have been nominated as a WHO Collaborating Center.

INTRODUCTION

(Min. 00:06:34)

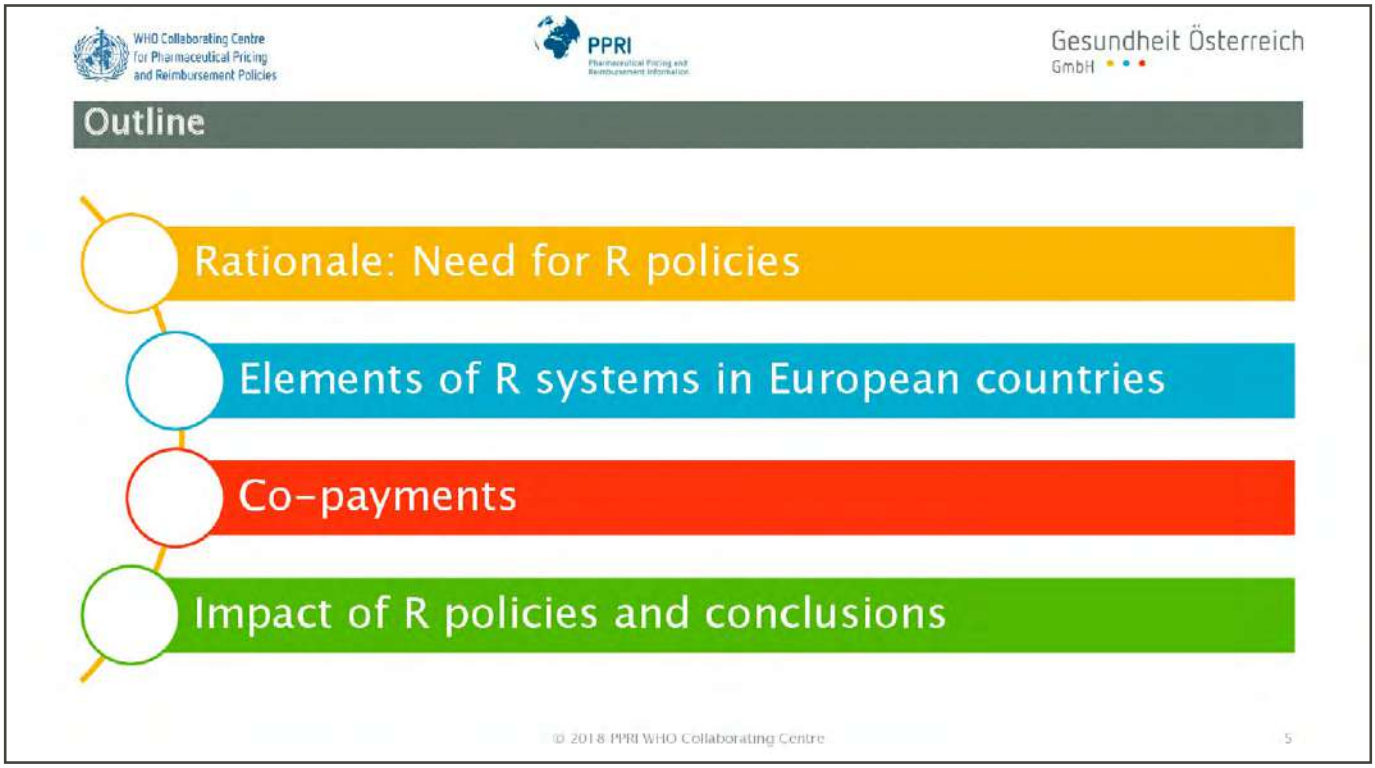
What I am going to talk about now is this report, which you see here, called "Medicines Reimbursement Policies in Europe". You also have the link. It was a report that we did for and together with WHO, with the regional office for Europe. And what was its content? The objective was to provide a comparative review and analysis of the different pharmaceutical reimbursement policies that countries in the WHO European region use, and to identify practices that protect vulnerable groups from excessive payments. This report has different contents and one is a review and description of the reimbursement systems and policies of forty-five European countries. We also did some case studies in nine countries where we identified and analyzed more in detail some reimbursement models. We did a literature review in order to understand the impact of different reimbursement policies. We also had – and I will show you some of those results – an analysis of the financial burden of co-payments. We really looked at very specific medicines and for specific groups of people in nine countries. You can thus imagine that for doing so we used different methods and, what I just explained on the previous slide, is that we have networks. This was

also helpful for this study because much of the information on the reimbursement systems was provided by the members of our PPRI network or, at least, validated by them in the cases where we collected that information earlier over the years but we validated and updated it. Also we are currently building up a new PPRI in the CIS countries. Those are the countries of the former Soviet Union. Therefore, the Commonwealth of Independent States, they also provided information. We had a literature review, we had interviews and it was good that we had access to price data that we could use.

DISCLAIMER AND ACKNOWLEDGEMENTS

(Min. 00:09:22)

Having said that, this is just a brief disclaimer slide. As usual I would like to stress that we are a WHO Collaborating Center, but we are not WHO and this is not a WHO presentation. I would also like to use this slide to give my thanks and acknowledgement to people who supported the study. These are my team members but also authorities in Europe that are members of the PPRI. I won't present the entire report to you, since it is a rather long report, but I will pick out some parts and present them to you.



OUTLINE

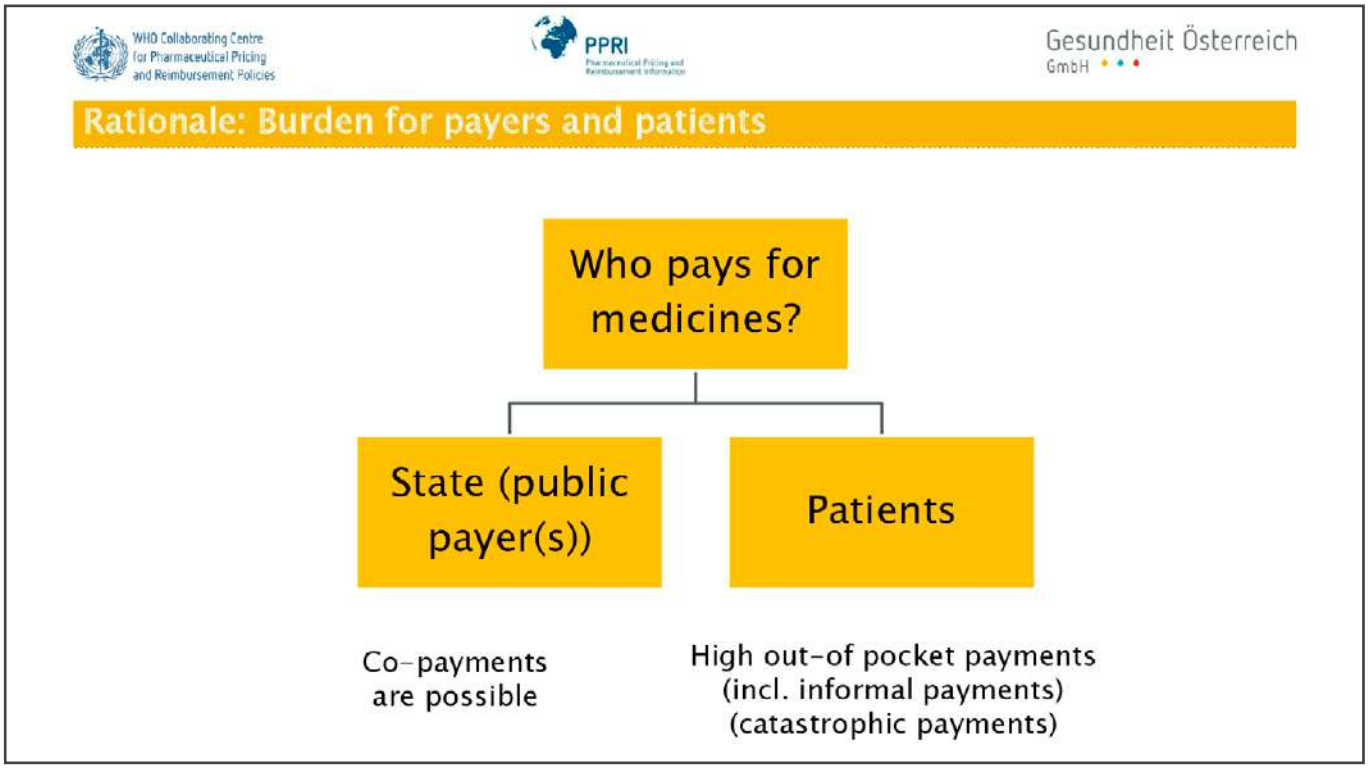
(Min. 00:10:14)

My presentation is structured as follows. In the beginning, I would like to explain why there is a need for reimbursement policies for medicines. This then will be followed by picking out some key elements of policies for reimbursement of medicines that we found and are frequently used in European countries. I will place a special focus on co-payments on what they look like in European countries and what is their impact. Finally, I will have a look on the impact of these policies and what we can conclude from them.

RATIONALE: SDGs

(Min. 00:11:05)

Let me start with the rationale for this study. I think you are all aware of the Sustainable Development Goals (SDGs), and particularly the SDG 3 on health and wellbeing, where we have one goal that clearly states to achieve universal health coverage, including financial risk protection, access to quality essential health care services and to safe and effective quality, affordable essential medicines and vaccines. I would also like to share with you a picture of the so-called “Framework for Collective Action” that was developed by WHO in 2004. Maybe you have already seen it. It makes clear that for having affordable access to essential medicines different dimensions are needed. You see here on the left side the rationale selection and that this has very much to do with the reimbursement, so which medicines to prioritize to have them made available to the population through solidarity based systems and to ensure that really the most effective medicines are made available. This is a key issue of reimbursement but also part 3 on funding is also key. I would like to follow up a little bit on it by talking about funding. But you see, of course, that affordable prices – and I will come to this link between price and reimbursement as well – and sustainable health and supply systems do play a role.

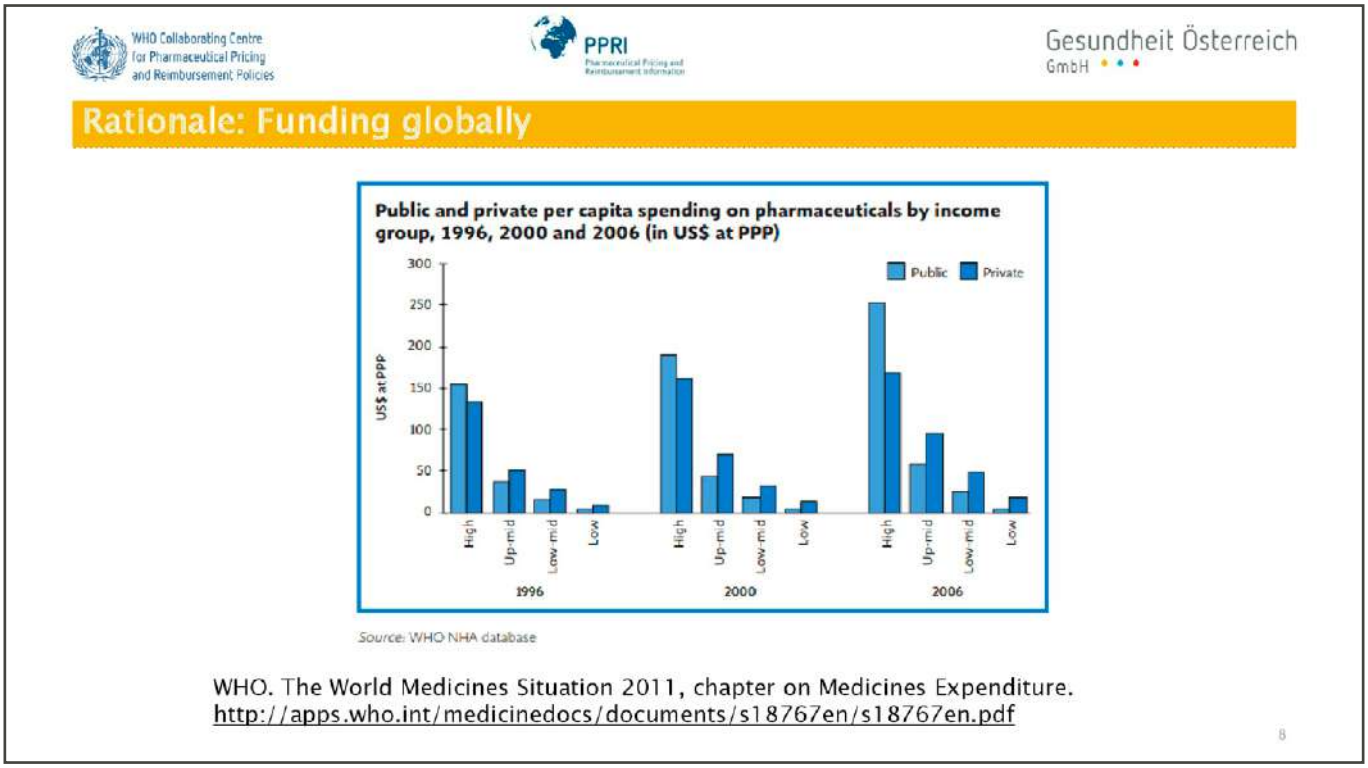


RATIONALE: BURDEN FOR PAYERS AND PATIENTS

(Min. 00:13:04)

The question is: who pays for medicines? I would say there are two key actors. One key actor is the patient. In many countries, including countries that you represent, it is the patients that have quite a lot of high payments, either they pay fully out of pocket for the medicines that are not part of the benefit package scheme, or even for medicines that are in the benefits package scheme where co-payments are still possible for patients. This is just the formal part. Of course, we are well aware that there are also informal payments. And the payments by patients are an issue for them and it can, as I will also show later, imply quite some burden for them and lead to catastrophic payments. That is one issue: how can we design the systems in a way that patients have access to medicines without a financial burden that eventually makes them decide to forgo medicines?

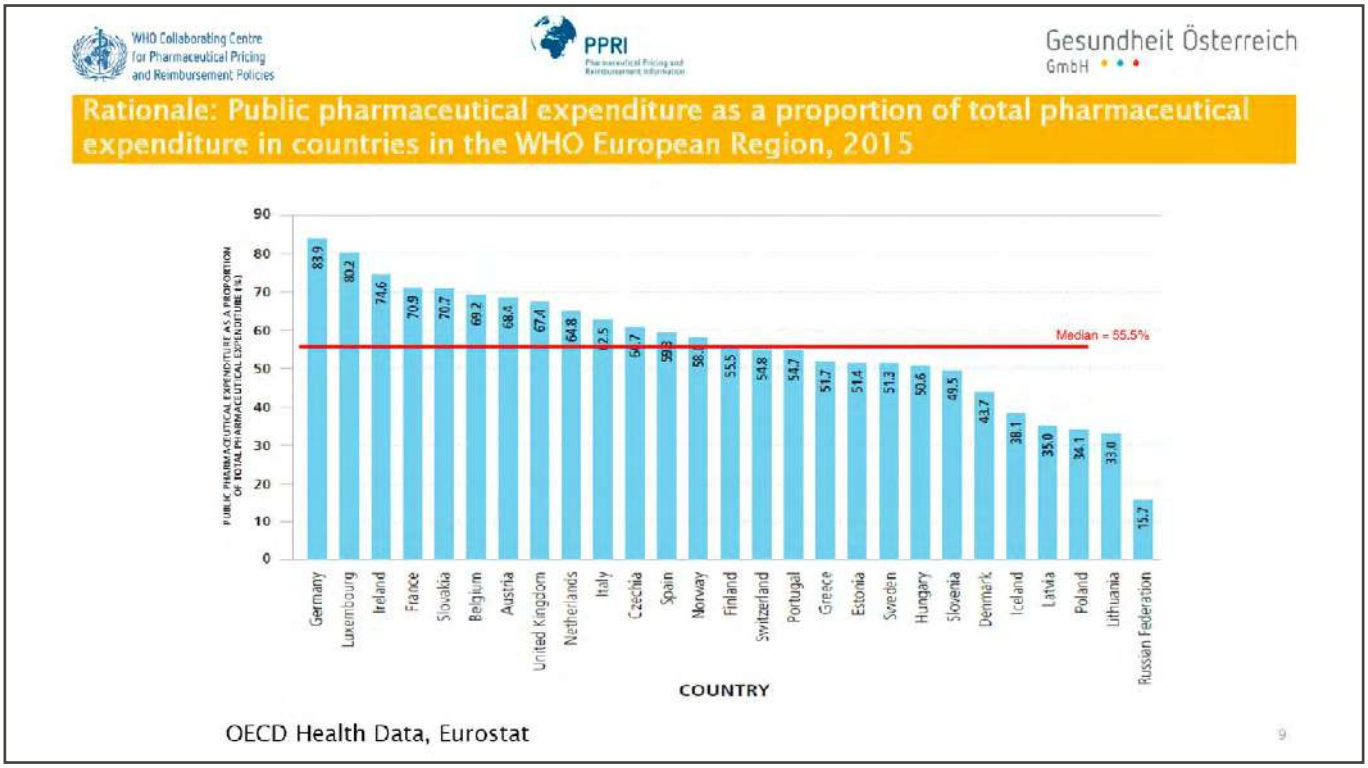
The other part is that third party payers, public payers/the State, pay for parts of the medicines. Here there is also the question of how to find a good way of selecting medicines. That is the other element.



RATIONALE: FUNDING GLOBALLY

(Min. 00:14:50)

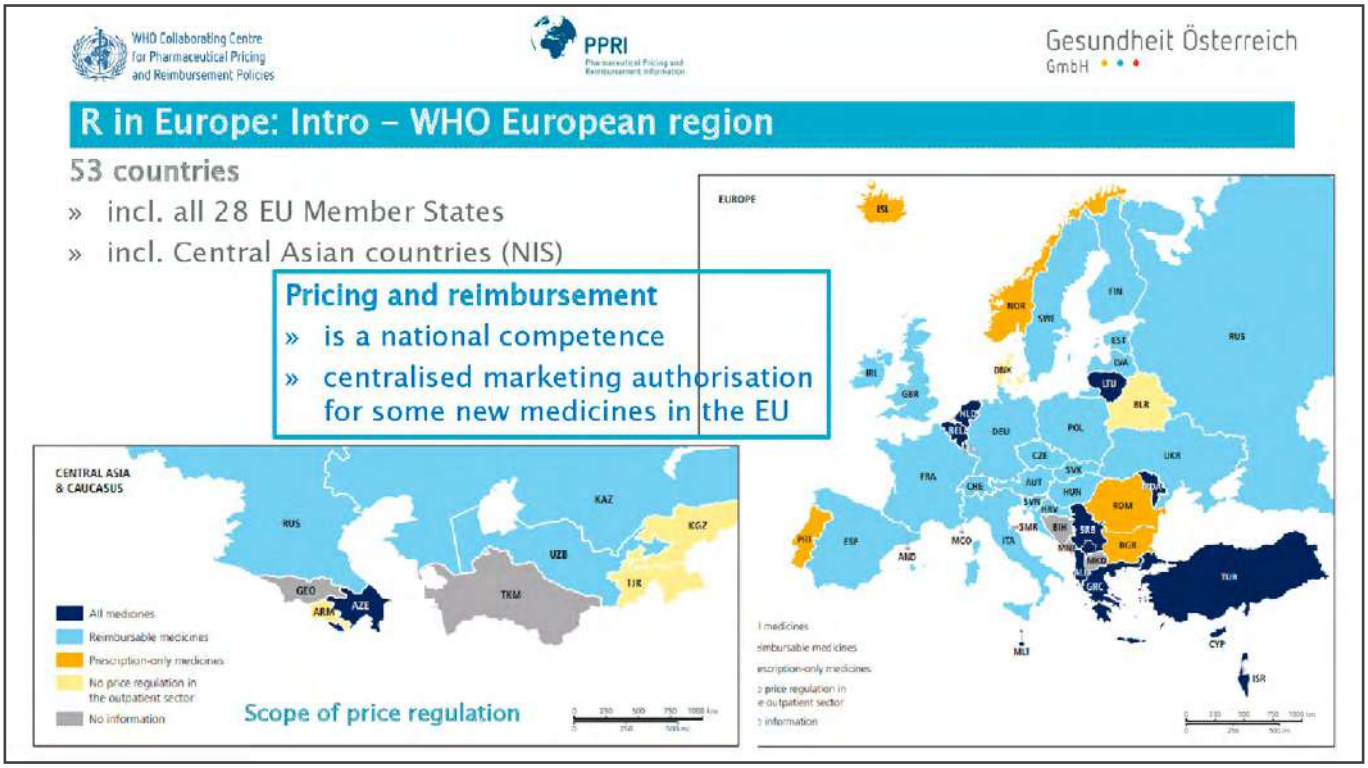
This is not part of the report but it is a very old information of the world medicines situation in 2011 that shows data of 2006 because in order to get information regarding the entire world we unfortunately do not have very much updated information. Here you see the blocks for high-income countries, upper-middle income countries, lower-middle income countries and low-income countries. You can see how things evolve over time and that it was particularly the high-income countries that invested more on pharmaceutical expenditure. But what you also see quite clearly is that it is in the high-income countries, as we have several of them in Europe, where there is a higher share of public pharmaceutical expenditure than private pharmaceutical expenditure. But when it comes to middle- and low-income countries the ratio is diverse, so the share of private pharmaceutical expenditure exceeds the share of public pharmaceutical expenditure.



RATIONALE: PUBLIC PHARMACEUTICAL EXPENDITURE

(Min. 00:16:10)

I would now like to share with you information about how this looks like in the countries of the European region. I will then tell you how we define the European region. Here you see the share of public pharmaceutical expenditure as part of the total pharmaceutical expenditure. The median is 55%. But you also see on the left side that countries like Germany, Luxemburg, Ireland or France have a higher share. And when you look at the right side it is rather countries with a lower GDP like Lithuania, Poland or Latvia where the part, which is publicly funded, is lower.



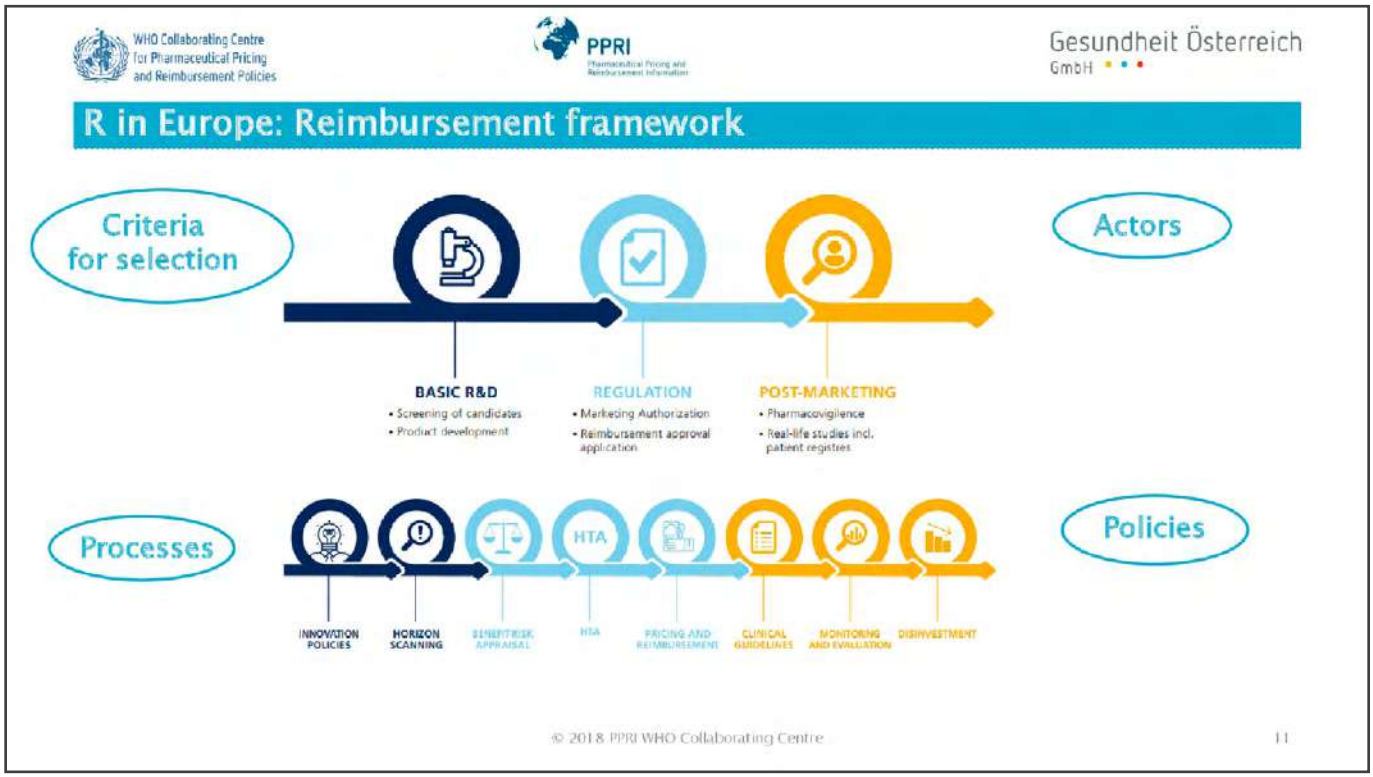
WHO EUROPEAN REGION

(Min. 00:17:20)

I just mentioned the WHO European region, but what does this mean? When you think about Europe you probably think about Europe as you see it here on the screen in the large image on the right side. At the moment still 28 countries are members of the European Union. But the WHO classification includes also countries which geographically are countries of Central-Asia. These countries include also the Newly Independent States as they are also called, and different "stan countries" like Turkmenistan, Kirgizstan etc., which you see here on the left side. In this presentation, I will present results from the WHO European region, will also always include these countries of Central-Asia. And then you will see that I am not just talking about a region that has only or predominantly high-income countries, but with Central-Asian countries we also have countries that are not high-income countries.

I am showing you this picture on the one hand to make you familiar with the countries of the WHO European region but, at the same time, it also presents some results not on reimbursement

but on pricing. Pricing is also important namely the question if prices of medicines are covered, if they are submitted to price control or not. You see here that in many of the countries, which are in blue, there is price control or price regulation, not for all medicines but for so-called reimbursable medicines. These are those medicines that are funded, at least partially, by the State. And here you see very clearly this linkage between pricing and reimbursement. Another information I would like to share with you is related to Europe. I told you that there are 28 countries that are part of the European Union, but still the issue of setting a price/pricing and deciding on the funding, on the coverage and the amount of coverage of medicines or reimbursement, is a national competence in Europe. Even in the countries of the EU. Therefore, each country decides on its own about pricing and reimbursement. When it comes to the marketing authorization, which is when it is decided if the product is allowed to enter the market, if it is safe, effective and of high quality, in this area we do have some harmonization in the EU. For some of the medicines there is a centralized authorization and for others there is cooperation with decentralized marketing authorization. But as far as pricing and reimbursement are concerned these are a national competence even in EU member states.



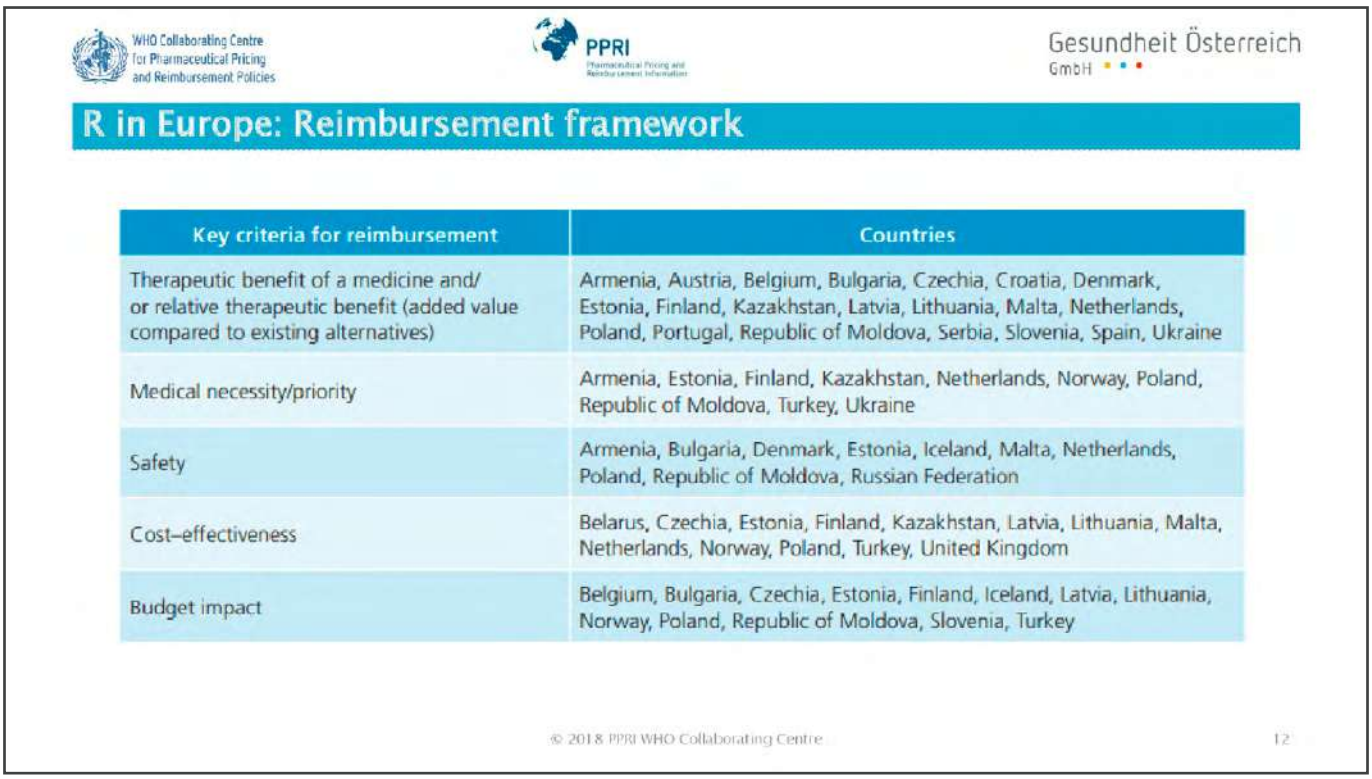
REIMBURSEMENT FRAMEWORK

(Min. 00:21:05)

So how does this reimbursement look like? This is a very simplified way of showing it. The light blue color describes the parts where reimbursement is situated. The dark blue is what comes before, like doing research and development or processes where the authorities look at the pipeline to see which might be new products that are coming, which is the so-called "horizon scanning" in order to be prepared for reimbursement. And the right side is what comes afterwards. As soon as the medicine is brought on the market there is a system of pharmaceutical vigilance, follow-up, clinical guidelines and there might even be some disinvestment. The light blue part is the decision that has to be made with regard to pricing, to reimbursement and it includes questions like: does the medicine have a certain value? How do we assess this value? Do we have tools like pharmaco-economics or health technology assessment that help us?

With regard to this framework there are different actors that are involved on behalf of the authorities. These are ministries and also reimbursement payers, which in European countries

are either social insurance institutions or national health services. Further actors that play a role might be pricing committees, reimbursement committees or a setup of different stakeholders that support the decision. So there are different actors involved. There are different criteria for selection, which I will present in a minute. There are different processes that are ongoing, for instance timelines can play a role. For the countries of the EU member states I said that this is a national competence. But there is one EU directive, which talks about certain minimum standards for the processes. For instance, one standard is that the decision on pricing and reimbursement has to be taken within 180 days, 90 days for pricing and 90 days for the reimbursement decision, or 180 days if the decision is taken jointly. This is one thing that is expected. Another one is that the processes are clearly transparent and that it is clear how the decision is justified and the decision is published afterwards. These are matters of processes. Another issue is the different policies and I will present you some key reimbursement policies.

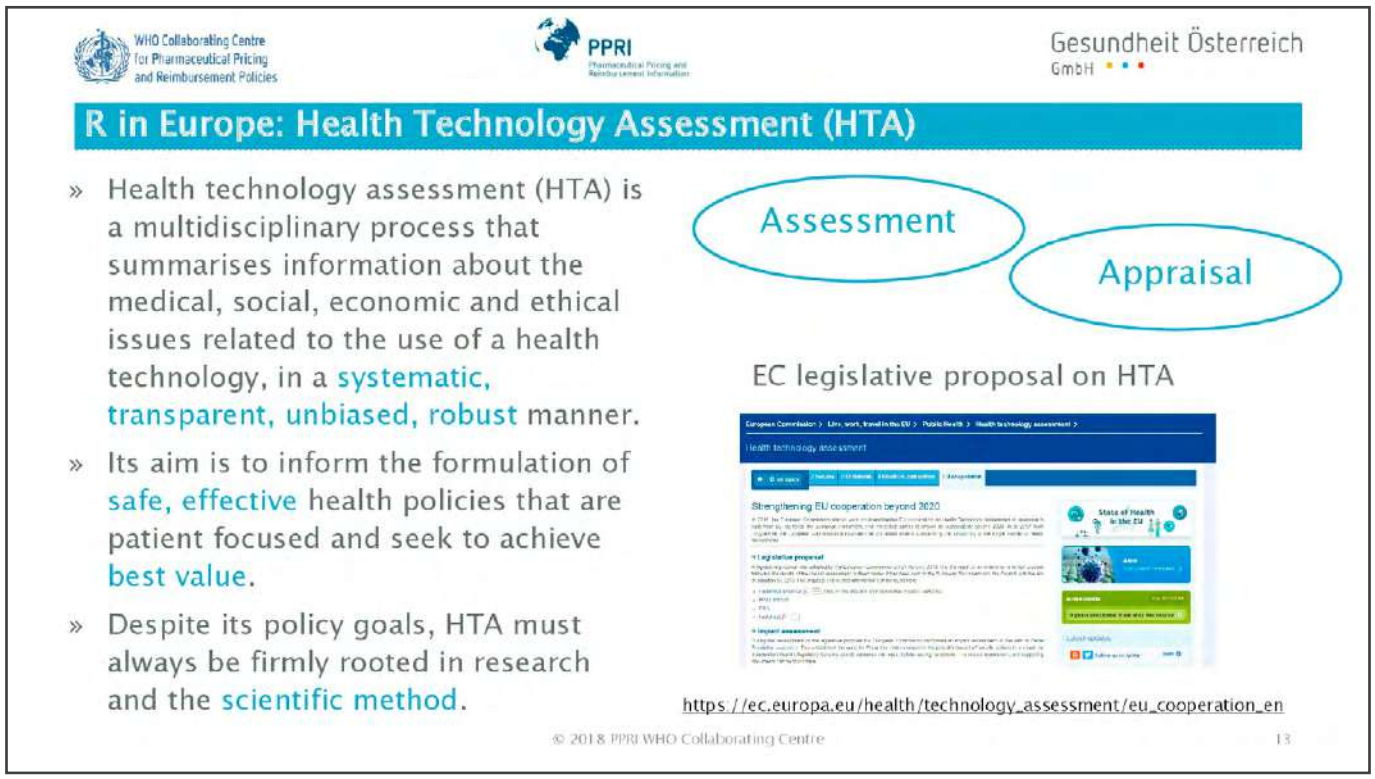


ESTIMATING THE OPPORTUNITY COST

(Min. 00:24:49)

I said that I would talk a little bit about criteria for selection. How do European countries decide on which medicines they want to include in the benefit package scheme and which not? Usually these criteria are established in the legislation and the key issue is the therapeutic benefit of a medicine, in particular its added value/its added therapeutic benefit, so in comparison to comparators. I would say this is the key criterion. Some countries also include the issue of necessity, which relates to the question of medical need. Some include regulatory issues like safety or cost-e ectiveness. You could also say that cost-e ectiveness is one technical way to assess this added therapeutic value. And there is another aspect, which I would say is rather new, that is the budget impact. This has to do with the rise of highly priced medicines, that we have seen in recent years. There was also the discussion of the feasibility or the effectiveness of the tools that we have in place for the time being. We might do a cost-effectiveness analysis and find out that this new medicine is cost-effective but we cant afford it. Or even if we decide to cover it, and this is also an issue for rich countries, then we can afford it in the short run but the financial

sustainability of our solidarity-based system would be impacted. So the issue is that it can be cost effective but it is still not affordable. The budget impact is becoming more and more an issue.

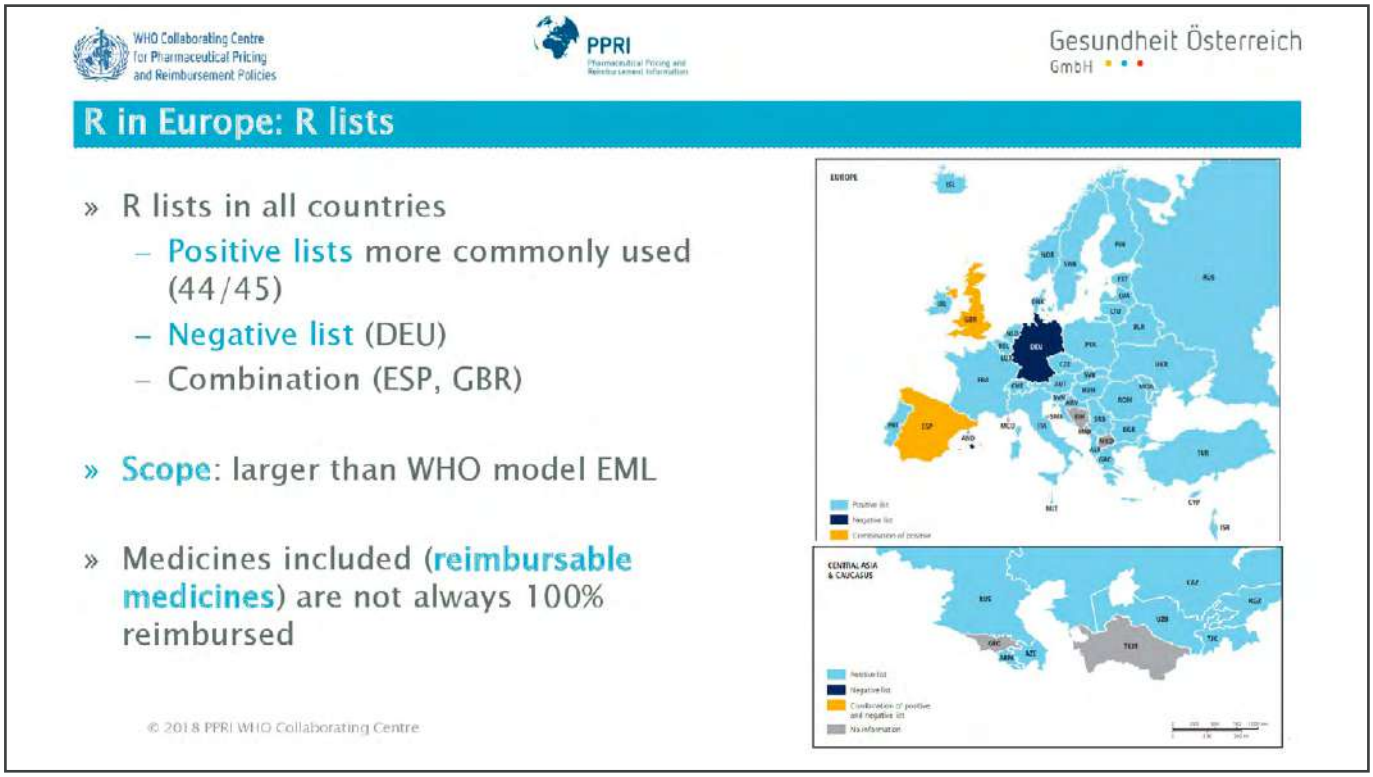


HEALTH TECHNOLOGY ASSESSMENT

(Min. 00:27:09)

In this sense HTA (Health Technology Assessment) plays a role. There is sometimes the idea that HTA would be the ideal solution for everything. It has to be clearly said that HTA is a tool. It is a supportive tool. It is not even a policy of its own but a tool, which is a multi-disciplinary process that summarizes information about medical, social, economic and ethical issues related to a medicine or some other health technology in a systematic, transparent, unbiased and robust manner. Its idea is to inform policy makers to take a decision. And what is very important regarding HTA is that there is a distinction made between an assessment, which is the technical part to look at the evidence, and then it has to be appraised. So HTA is a supportive tool and in Europe there is currently quite some discussion ongoing. We had some collaboration on HTA in recent years. There is also the idea that while the final decision on prices and reimbursement

is an individual decision by the member states, the first steps regarding the clinical assessment of the medicine is something where there is no need to redo it and collaboration would be great. We have a network, which is the EUnetHTA network of HTA bodies and member states but also stakeholders, which has been working on methodologies and on how to improve the collaboration. This network receives some EU funding but it will run out in 2020. The European Commission has been discussing how Europe shall move on with HTA in the future. There were different suggestions or models. There are discussions on how strong the collaboration should be or if it should just imply more coordination. Currently, since the end of January of this year, there is a legislative proposal on collaboration of HTA on the table and it is currently being discussed. I assume it will still take quite some time, maybe around two years, until some conclusion can be reached. This is currently a major issue of discussion in Europe.

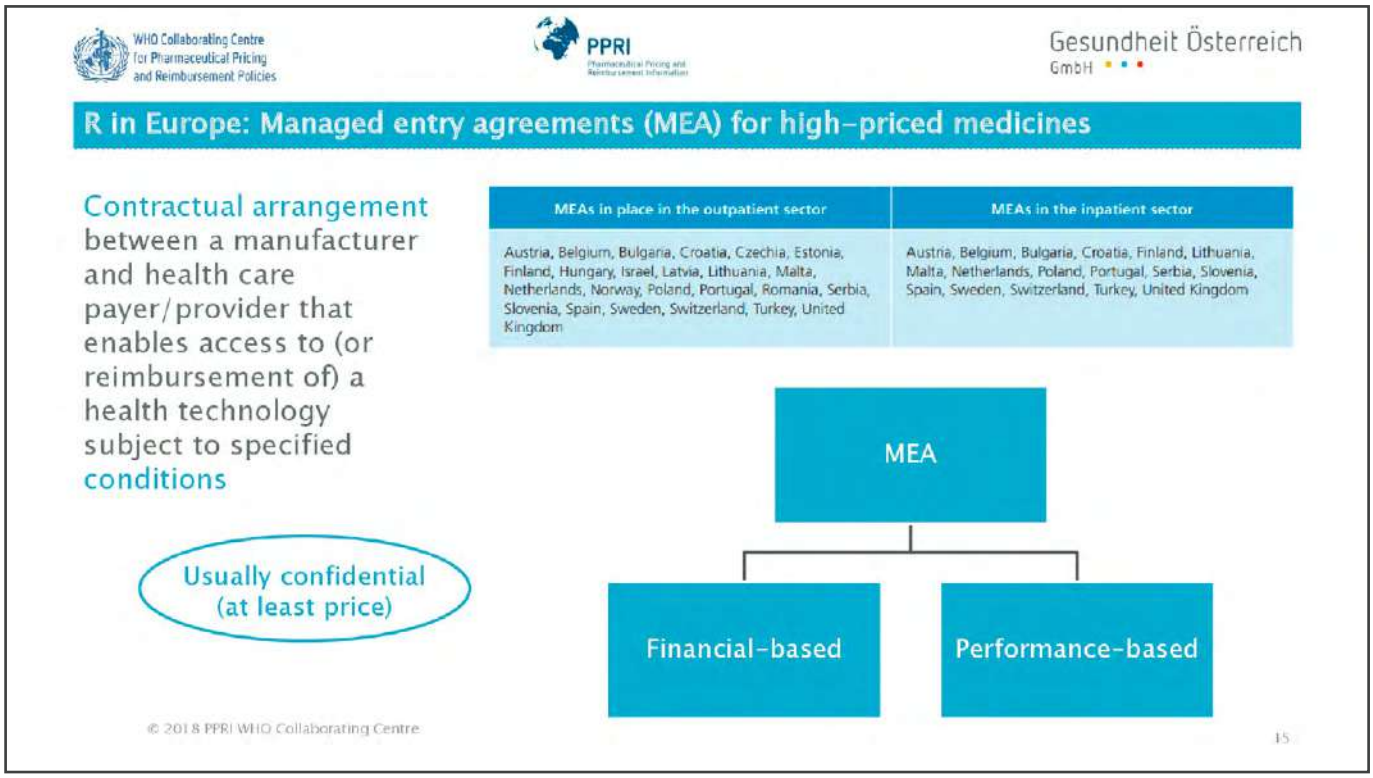


REIMBURSEMENT LISTS

(Min. 00:30:06)

I will now talk about different policies, which are used in Europe. There are reimbursement lists that are used in all countries. The most common way of using them are so called “positive lists”. This means that those medicines that are covered by the public payer are listed. That is the way that 44 out of the 45 countries surveyed do it. Germany has an explicit negative list, which explicitly excludes those medicines that are not covered. Spain and Great Britain have a combination. One could argue that the EML (Essential Medicines List) of the countries is kind of a national EML. However, in European countries the term EML is not that frequently used. Rather we talk about reimbursement lists or positive lists. One can also say that when you compare the content of the reimbursement lists to what is included in the WHO EML model, the scope in European countries is rather large. You also have to be careful when you compare the picture of the different parts within Europe. Central- and Asian- European countries also have positive lists, there they are rather called EMLs, but their lists are much smaller than in the high-income countries. In high-income countries this list sometimes has 3,000 to 5,000 medicines. In countries in Central-Asia it might have 60 or 80 medicines on the list. An important point that I would like

to make is that medicines that are on the reimbursement list are reimbursable medicines but this does not mean that they are always a 100% reimbursed. There might be co-payments. I will talk about that a little bit later. It might be that one portion of the price is covered by the public payer and the rest has to be paid by the patient.



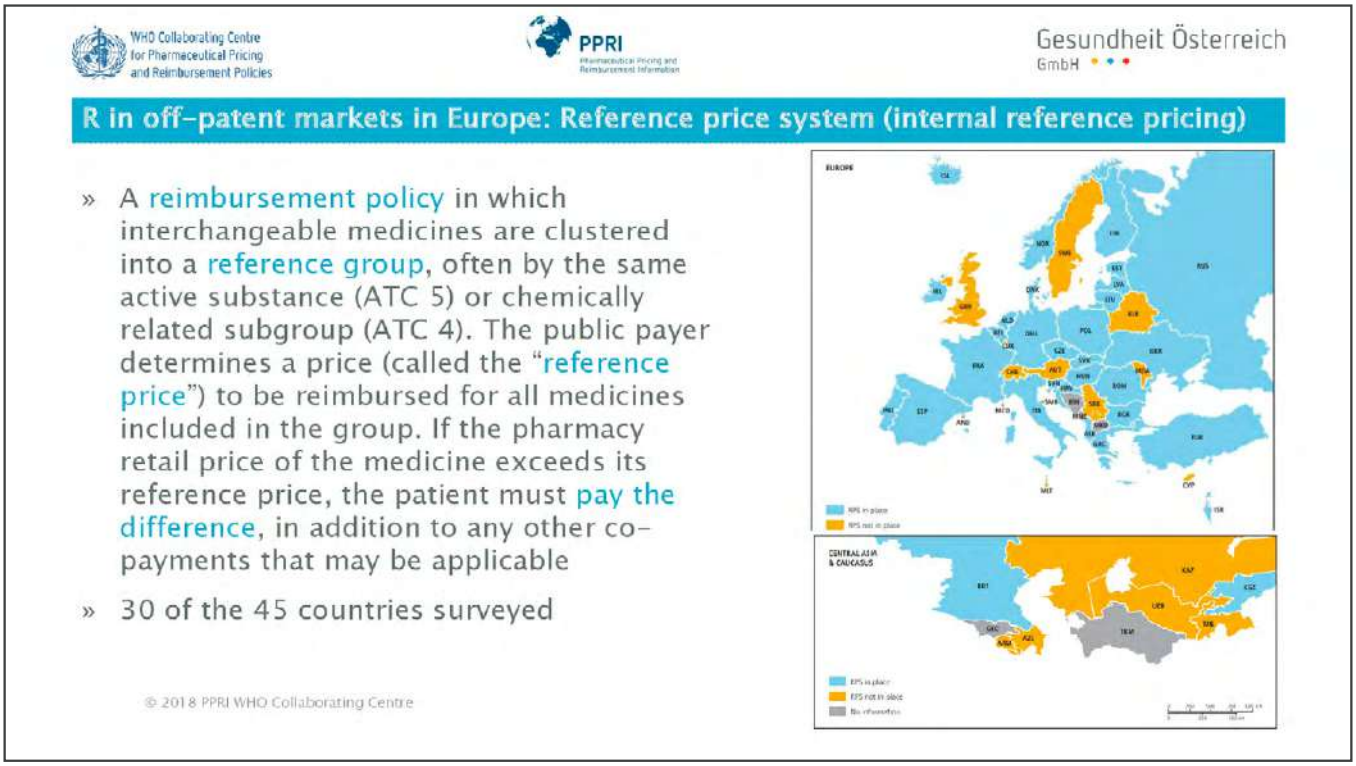
MANAGED ENTRY AGREEMENTS

(Min. 00:32:55)

I would like to present you one instrument that is nowadays really very commonly used in European countries. As I have said before we are facing the challenge that in recent years more and more highly priced medicines have been coming onto the market. Countries that struggle with their budget face the problem that they can't pay for them. Even high-income countries struggle with these medicines as they challenge sustainability. In recent years so-called "Managed Entry Agreements" have been used more and more frequently. These agreements are established between the pharmaceutical company and the public payer, where under certain conditions these medicines can be used. You can see here that they are frequently used in many

countries. We know that at least 24 countries use it in the out-patient sector and 17 countries in the in-patient sector. You have maybe heard of these Managed Entry Agreements before under different names like Risk-Sharing Agreements and things like that. The important thing to understand is that there are, on the one hand, financial based Managed Entry Agreements, which include simple discounts, price-volume agreements or utilization capping; and on the other hand, performance-based Managed Entry Agreements. The idea of performance-based Managed Entry Agreements is that they are linked to the outcome, whether the medicine is successful or not. Also, patient registries play a major role here.

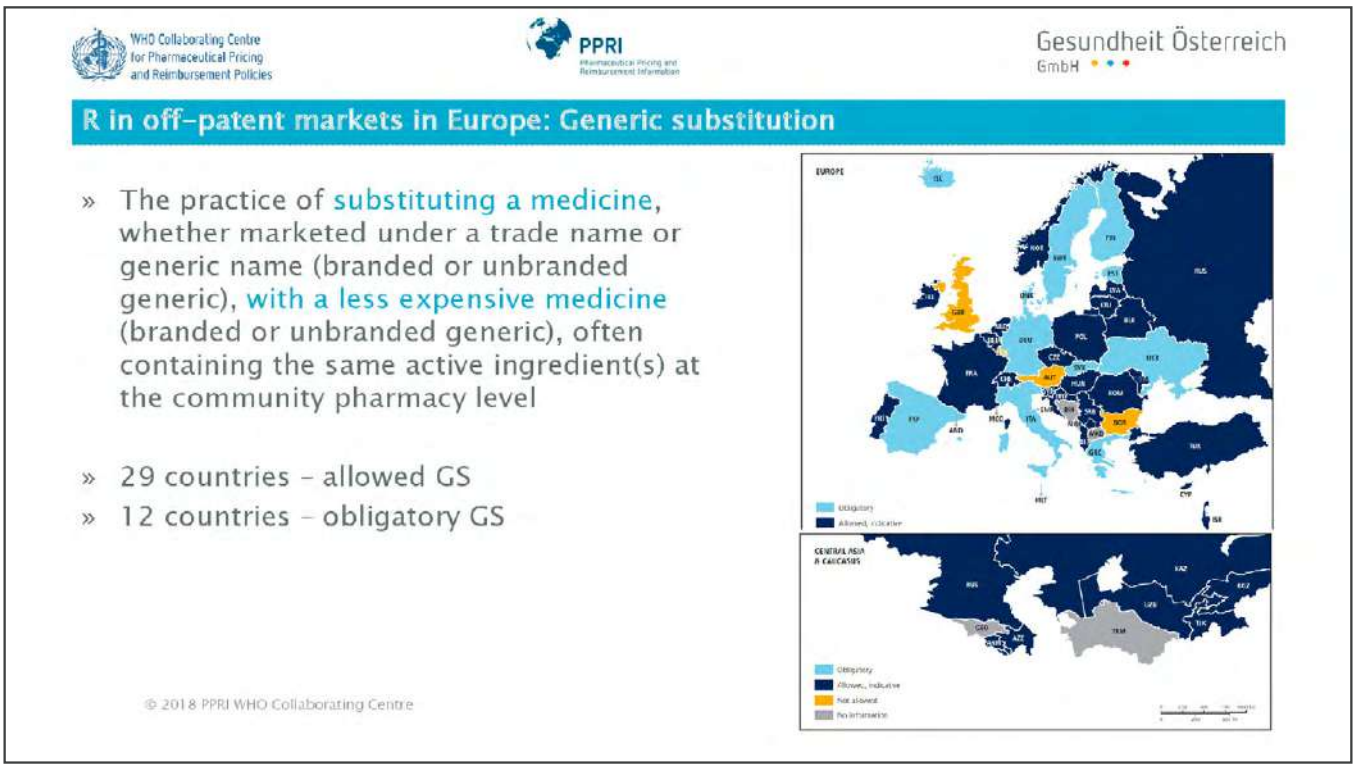
This is particularly an instrument for highly priced medicines as I mentioned before. But they are very strongly linked to the confidentiality price, which is negotiated and always confidential. Yet, in many countries even the type of agreement is confidential. We do not know if it is a risk-sharing agreement or a discount, financial-based or performance-based, etc. In some countries, we even do not know which medicines have this Managed Entry Agreement and which not. This is a mayor issue because when you think about pricing, many European countries price medicines based on the prices in other countries, which is referred to as external price referencing. But, of course, they refer to the official list prices so they overpay for them. If they can't pay for them, they need Managed Entry Agreements. You can see that it is rather complicated.



REFERENCE PRICE SYSTEM

(Min. 00:36:30)

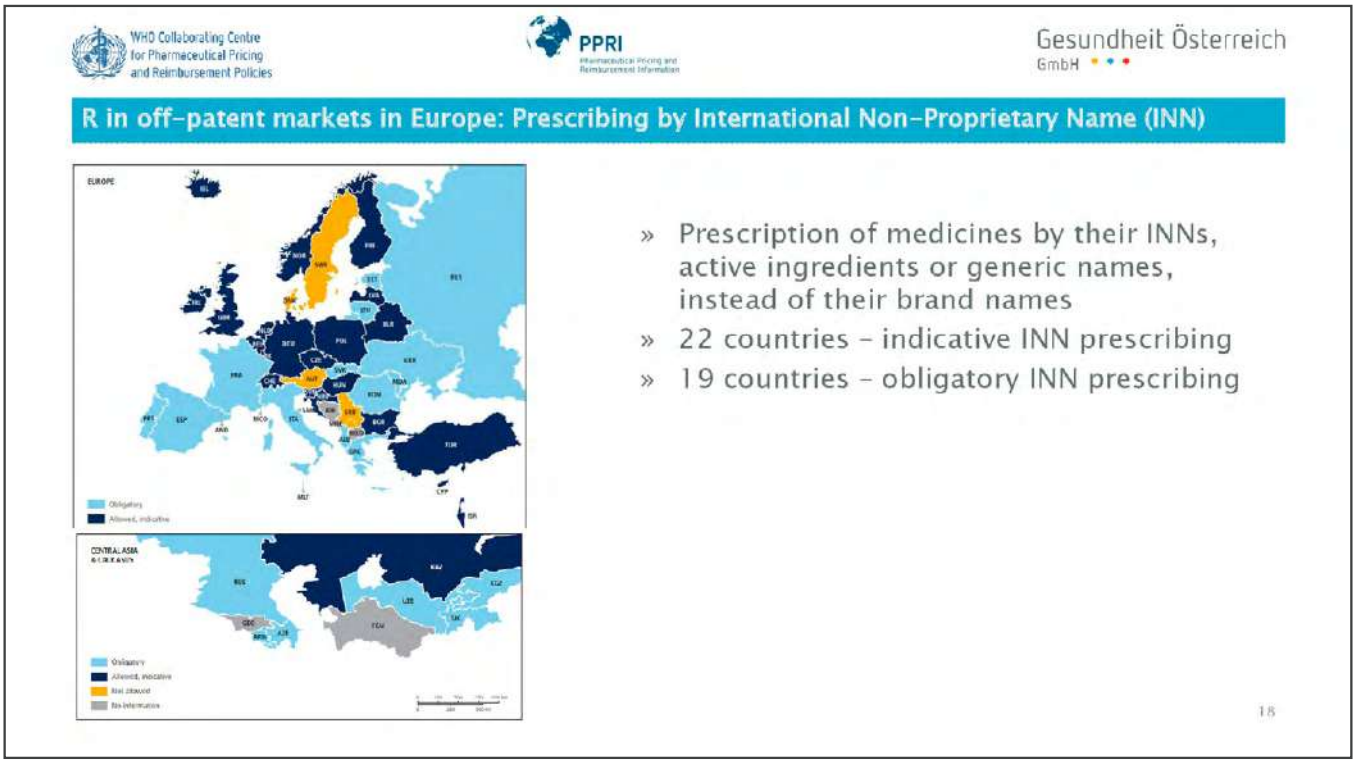
Regarding the off-patent market, the market of off-patent medicines, there are some other policies that are frequently used. One is a so-called "Reference Price System" or "Internal Reference Pricing". It is a reimbursement policy even though it has the term "price" in it, where clusters of similar or identical products are built. Either products of the same ATC 5 levels, the same molecule are clustered together or medicines that are substitutable. And then a certain amount, the reference price, is paid and if the patient wants a medicine in this cluster that has a higher prices it is up to the patient to pay for this difference. Thirty-five countries out of the forty-five countries that were surveyed have this type of reference price system. Of course, in terms of methodology there are different ways of how you can do it. Eighteen countries have medicines of the same molecule that are built into clusters, so rather small clusters, while twelve countries have a broader understanding of the cluster. Of course, when you have a broader cluster you can achieve higher savings, but it can be more challenging. When you newly introduce a new medicine you will probably start with the narrower clusters. It is also interesting to see in which way to establish this reference price. Shall it be the lowest price of the medicine in the cluster or an average? This can really make a difference.



GENERIC SUBSTITUTION

(Min. 00:38:37)

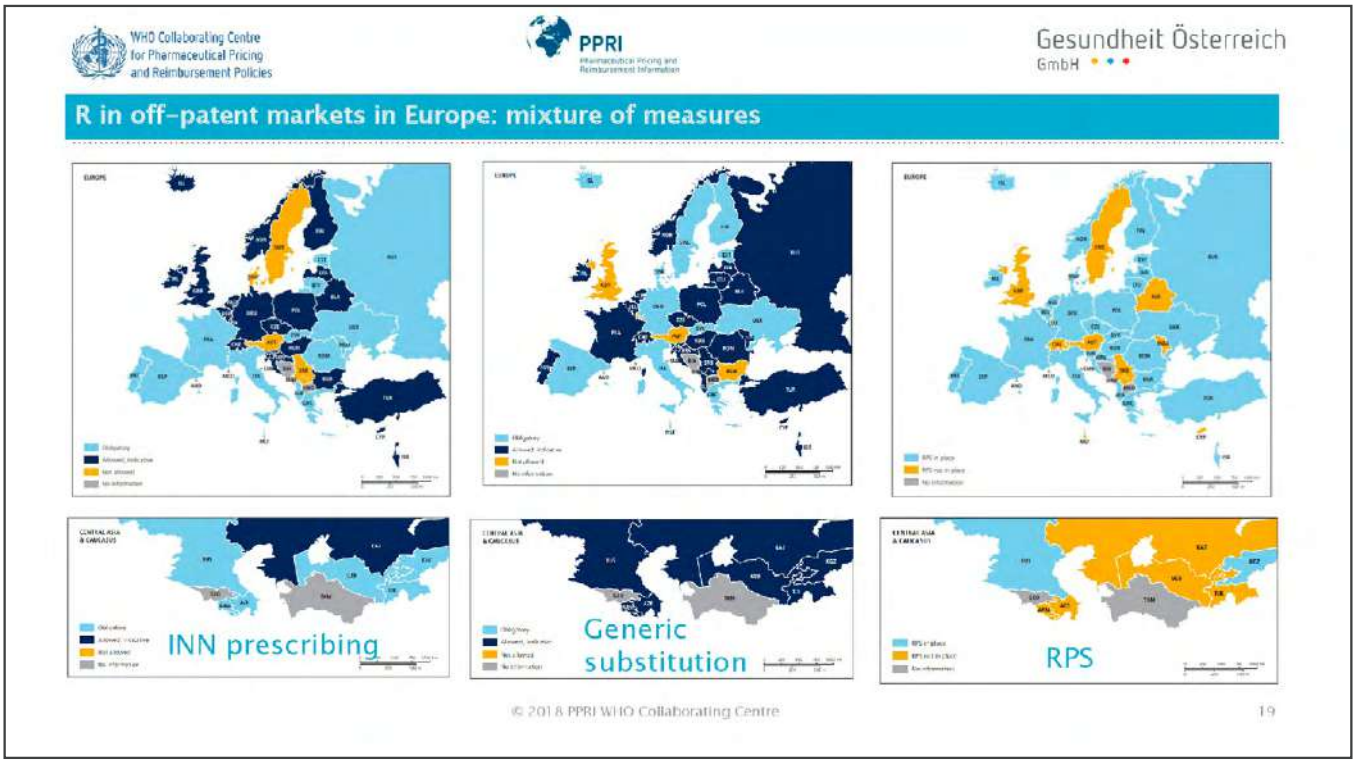
There are two other policies that I would like to briefly present. They are also linked to reimbursement in the off-patent market. Even if these policies are not reimbursement policies in the narrower sense, they are more demand-side measures that help reimbursement policies. On the one hand it is generic substitution which means that at the community pharmacy the pharmacist is allowed or is obliged to substitute the medicine, which could be an originator brand, by lower priced medicine like a generic product. As you can see this is a very common policy. Twenty-nine countries allow this policy on an indicative basis and in twelve countries the pharmacist is really obliged to do it.



INN PRESCRIPTION

(Min. 00:39:51)

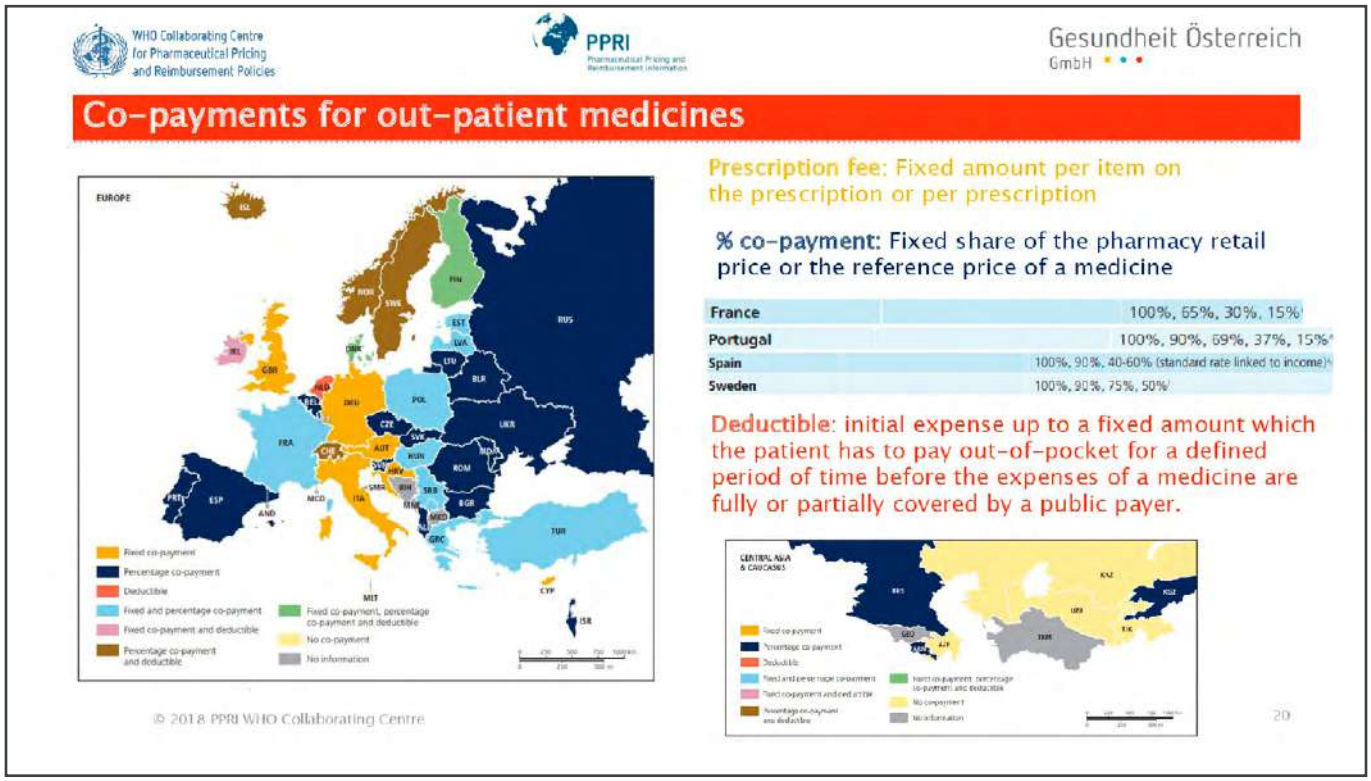
Generic substitution can also be done through INN prescribing, which means prescribing the non-proprietary name. That is an aspect that is addressed by the doctor. The doctor prescribes the active ingredient. Again you see here the way that it is just allowed is commonly used in 22 countries while nine countries use it on an obligatory basis. I also have to say that when countries start to introduce generic substitution and INN prescribing, first they usually do it on a voluntary basis but often that was then not enforced. This resulted in the idea to make it obligatory so the pharmacists or the doctors have to comply with it.



MIXTURE OF MEASURES

(Min. 00:40:45)

Here you have a slide where you can see these three policies of INN prescribing, generic substitution and reference prices next to each other. In the upper part you can see that several countries have at least generic substitution if they don't have INN prescribing. Very few countries don't have either but in principle it is commonly used.



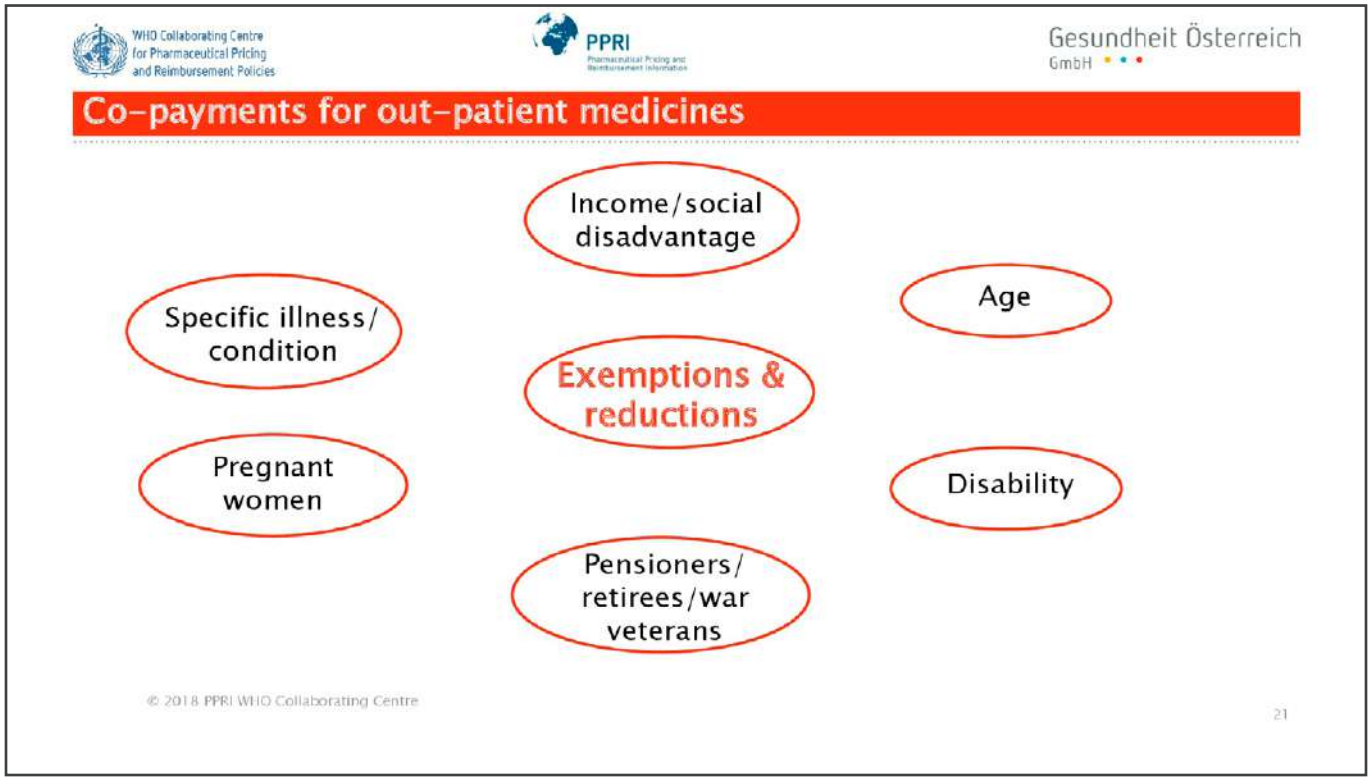
CO-PAYMENTS

(Min. 00:41:20)

I would also like to talk about co-payments because this is a mayor issue for patients. In hospitals normally there are no co-payments for medicines but there are co-payments in the out-patient sector. There are different types of co-payments. I would like to walk you through the different types. One type of co-payment is a prescription fee. This means that you have a fixed amount that has to be paid for each prescription or for each item of the prescription. For example Germany, Austria and Italy use this method. Some countries use it together with another type of co-payment. France, for example, uses it together with the percentage co-payment. It is in place in 17 of the 45 surveyed countries. I already mentioned before the fact that the medicine is reimbursable does not mean that it is automatically always a 100% reimbursed. There is also a so-called “percentage co-payment”. This means that certain medicines that are considered essential are reimbursed at 100% but for others the State pays, for example, 80% and the patient has to pay 20%. In cases where the medicine is considered to have a lower therapeutic benefit it might be 60% or 40%. This is really commonly used and 32 of the 45 surveyed countries have this

system in place. Less common is a so-called deductible. Deductible means that in the beginning the patient has to pay fully out-of-pocket up to a certain amount and when a particular threshold is reached then the medicine is covered by the public payer, at least partially. This method is not that commonly used. Only eight countries apply this policy. As you can see from the colors, combinations are really very common.

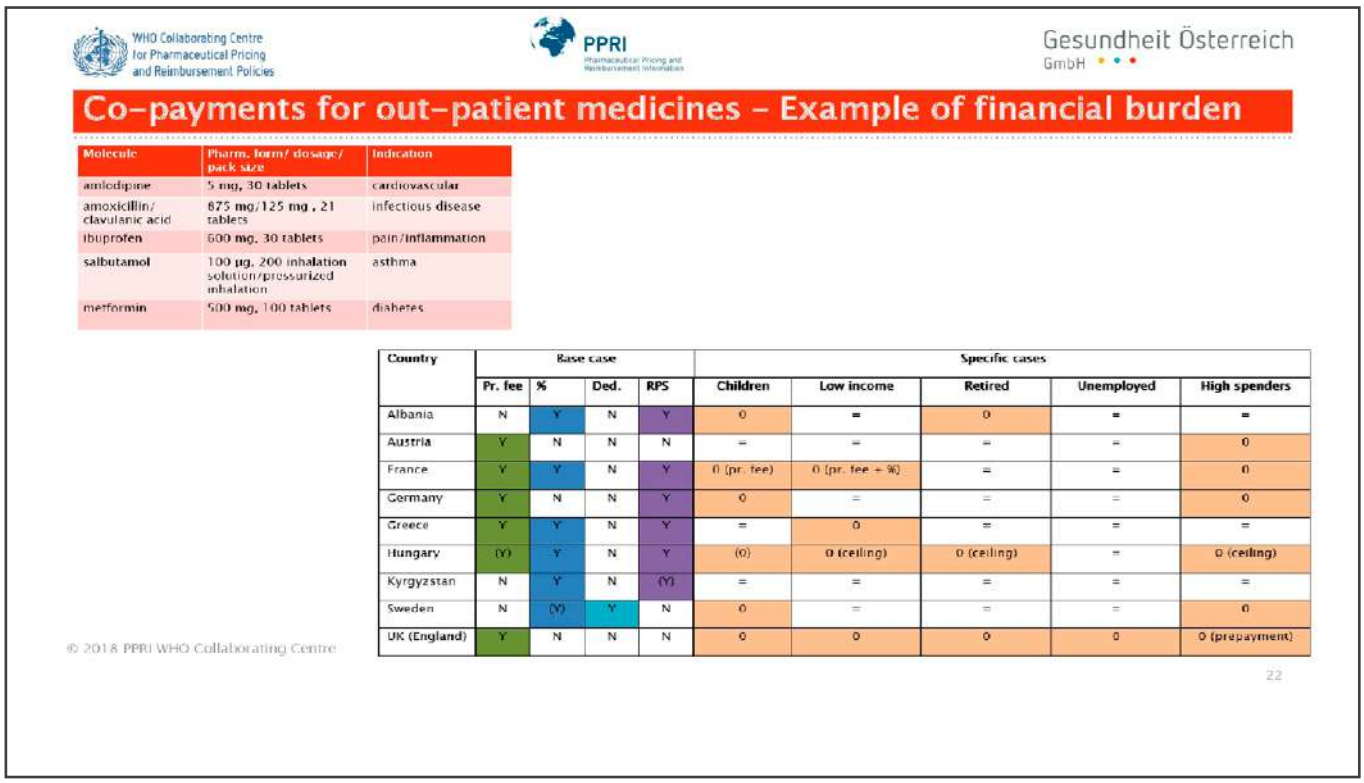
If you look at the map on the right side which shows the Central-Asian countries which are part of the WHO European region, you can see a picture which is maybe a little bit misleading because it says “no co-payment”. But you have to consider this is not out-of-pocket payment but co-payment for medicines that are in the benefit scheme. So in these countries there are no co-payments but you have to take into account that the benefit package scheme, as mentioned before, is a very limited one where you only 50 or 100 medicines are covered. And for all the others that are not included in the reimbursement list the patients have to pay fully.



CO-PAYMENTS: EXEMPTIONS AND REDUCTIONS

(Min. 00:44:41)

In most countries there are certain exemptions or reductions from co-payments. These are for people of low income or those socially disadvantaged. Age is also an issue. Children or elderly people might be exempted. Disability is another reason for exemption or reduction. Pensioners, war veterans or pregnant women are exempted. Several countries also decide that for certain conditions or illnesses patients should be exempted.



CO-PAYMENTS FOR OUT-PATIENT MEDICINES

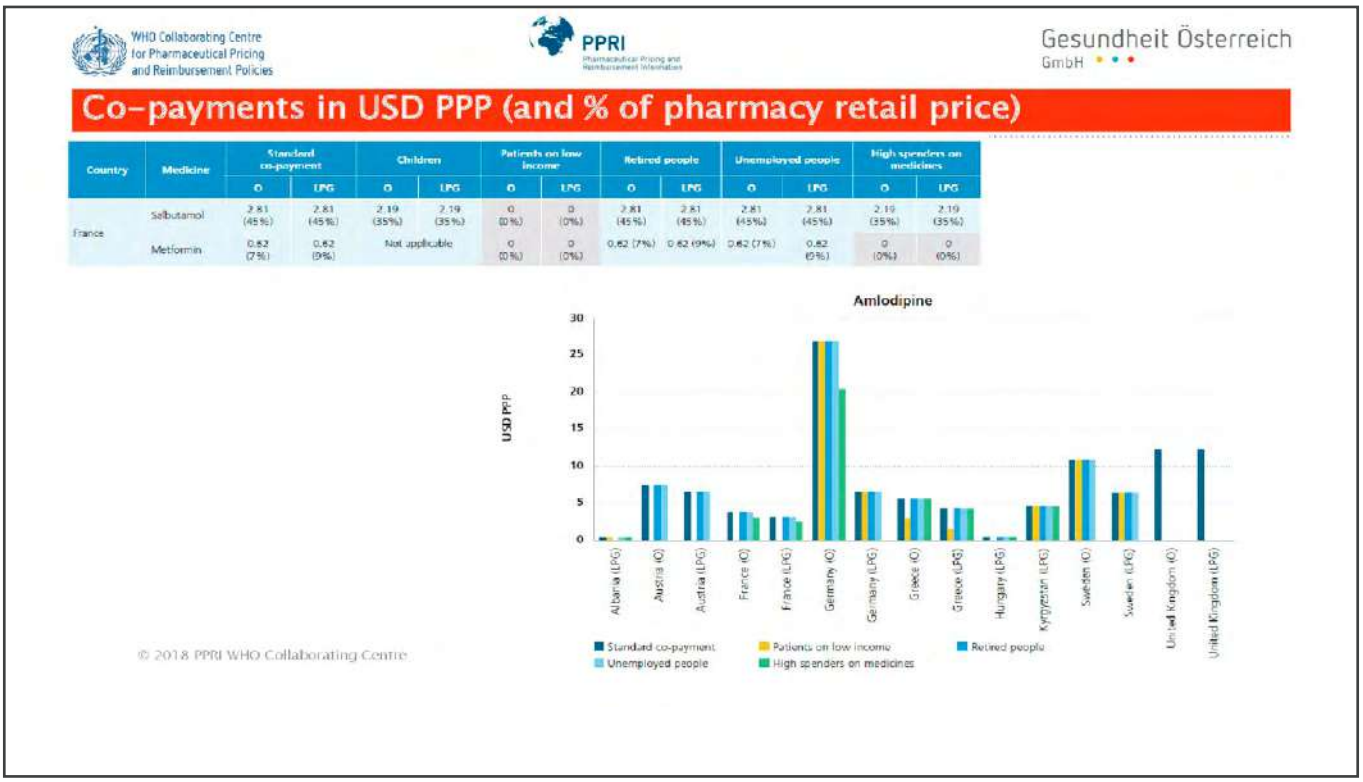
(Min. 00:45:25)

I would just like to briefly share with you some examples that we included in this study. We were interested in the following questions: what does this mean? How much are the patients affected by the co-payments? We looked at five specific medicines in the out-patient sector, including a cardio-vascular medicine, a product related to infectious disease, a painkiller and an asthma and a diabetes medicine and we chose nine countries. These are: Albania, Austria, France, Germany, Greece, Hungary, Kirgizstan, Sweden and the UK. Here you see the overview of which type of co-payment is in place in these countries. You can see that prescription fees are commonly used and that nearly all of the countries have percentage co-payments. This means that for certain medicines the patients have to co-pay a certain price. Deductibles are rarely used. Just Sweden has them. The internal reference price system is rather commonly use.

You can also observe here that we looked at special cases such as children, people with low income, unemployed and what we called “high-spenders”. This might be patients that are,

for instance, chronically ill, who spent a certain amount on medicines. We looked at all the exemptions or reductions that exist for them. You can see that exemptions for children are commonly used in these nine countries and also for people who are “high-spenders”. “High spenders” means that when they reach a certain ceiling they have no co-payments any more or fewer co-payments. Of course this ceiling differs between the countries.

You can also see that, for example the UK, often exempts several population groups. On the other hand, Kirgizstan does not foresee any exemption.



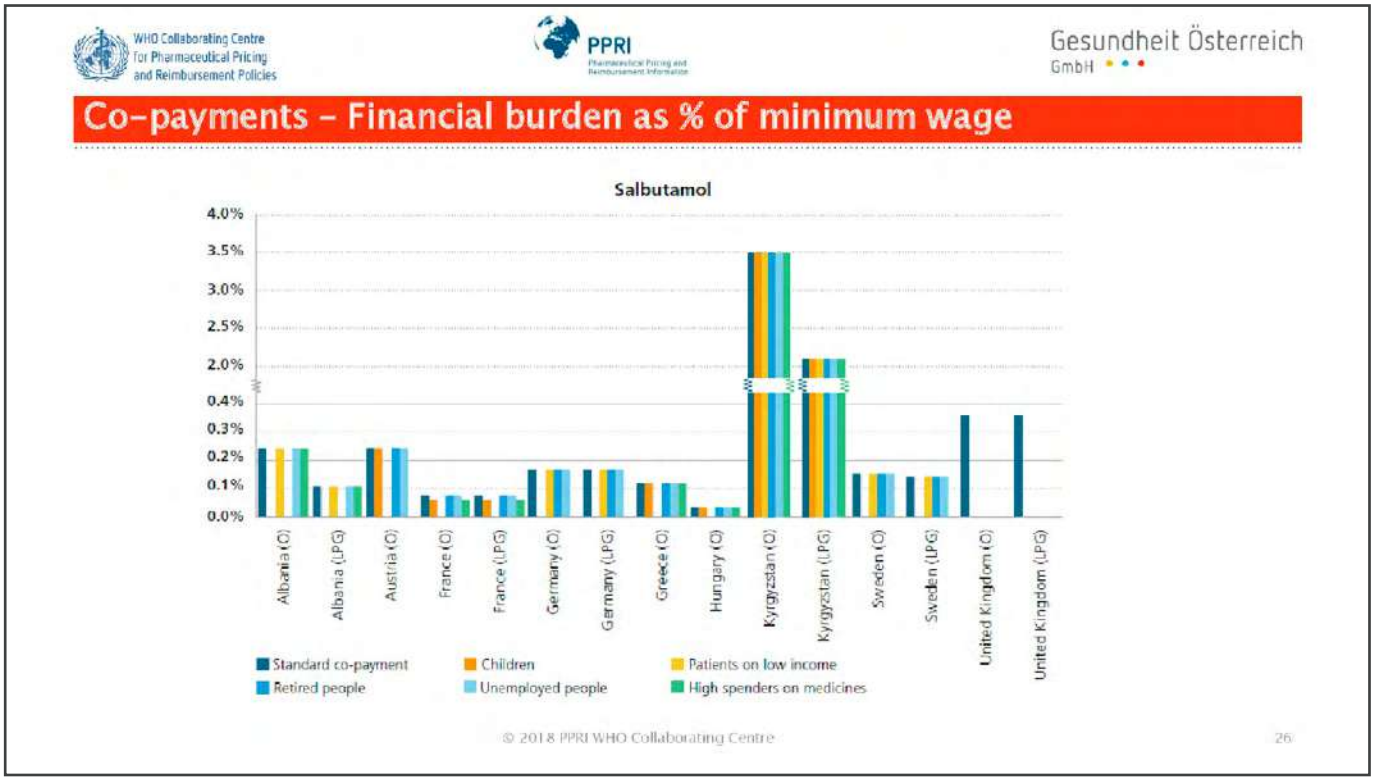
CO-PAYMENTS FOR OUT-PATIENT MEDICINES

(Min. 00:47:54)

Then we looked at different medicines, the five that we selected. We checked the pharmacy retail price, the co-payments that apply, the price that the public payer pays and the part that the patient pays. This can be a mixture of a prescription fee, a deductible or a certain percentage of the price. You can see here that it makes a difference, as explained before, for different

population groups. That is one thing you can see here. You can also observe in this graph that there can be a difference between countries. We always looked at the price of the originator and the price of the lowest priced generic. In the graph that I show you here, and this is also true for the next graph, only when price data was available these medicines were included in the graph.

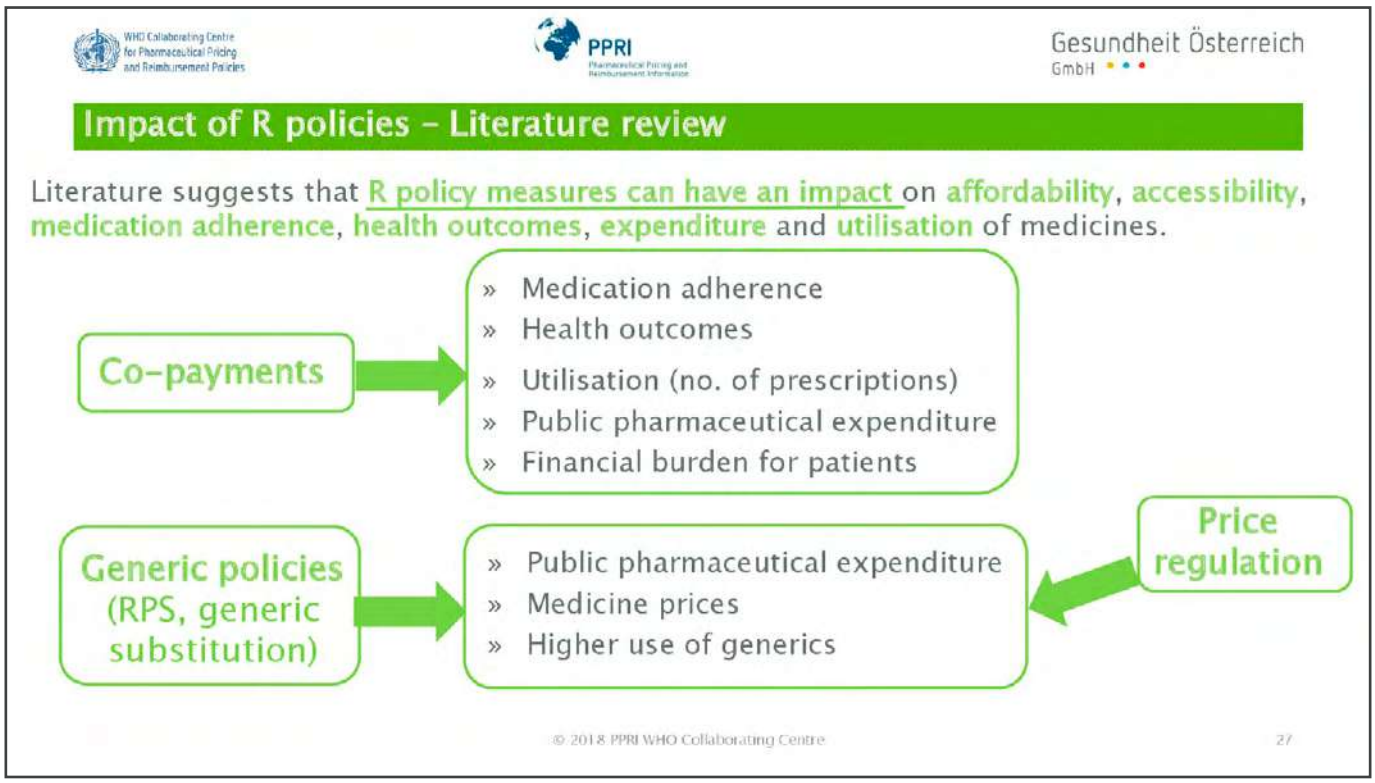
What did we do next? Then we took the co-payment for this specific medicine – I have to say that we calculated it for a therapy for one month for chronic diseases and for one episode for the acute care - and we looked what was the percentage of the minimum wage. For instance, if you look at Amlodipin you see here that for Kirgizstan, even if just the lowest price generic was available and the originator was not even there, one month of Amlodipin can constitute 9% of the minimum wage, which is, of course, quite shocking. For the other countries it is usually less than 1%. What you can also observe here is that Germany has a rather high share regarding the originator. We saw that with other medicines, as well that for the originator, it is rather high while for the generic it is rather low, which also shows in a certain way how the country supports generic policies.



CO-PAYMENTS: FINANCIAL BURDEN

(Min. 00:50:26)

You can see this again looking at other examples. Overall the picture was very clear. Kirgizstan is not in this graph because we didn't have data on their package scheme but in Albania it was rather high and also in Germany regarding the originator.

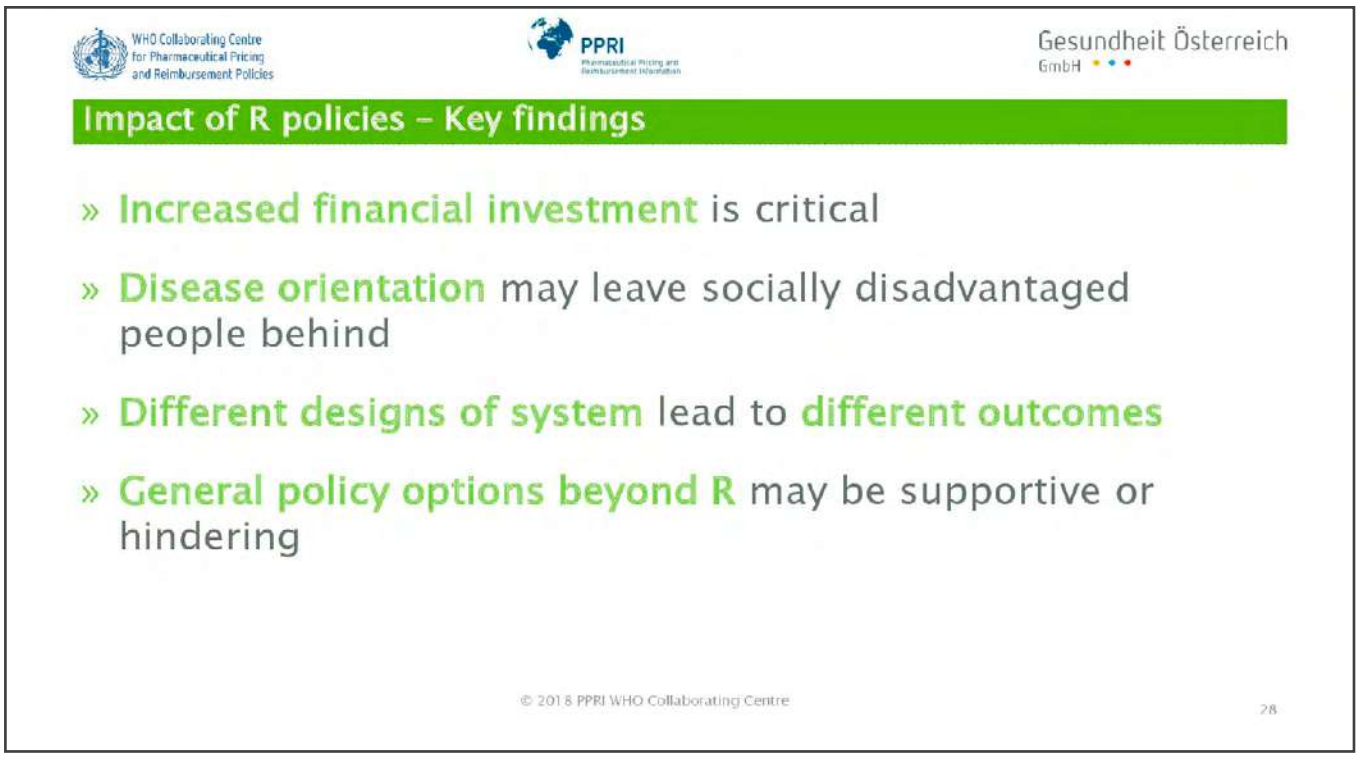


IMPACT OF REIMBURSEMENT POLICIES

(Min. 00:50:46)

I would like to come to the end of my presentation. One question we focused was related to the impact of reimbursement policies taking into account this burden, which we have already observed. We also had a look at literature. Literature suggests that reimbursement policy measures can have an impact on affordability, accessibility, medication adherence, health outcomes, expenditure and utilization. In the literature you can find mainly studies on co-payments and on generic policies. Regarding co-payments, it was observed that reduced co-payments can increase medication adherence and health outcomes. Co-payments have an impact on utilization and on public pharmaceutical expenditure. Generic policies can also have an impact on public pharmaceutical expenditure as well as on prices and on the increased use of generics. The point that I would like to make here, and we have seen this also in the case studies, is that generic policies are one element of reimbursement. But there is also the issue of prices. If countries have price regulations that also contributes a lot. If you think through the example I have shown you of the financial burden. Yes, of course with reimbursement policies and with the

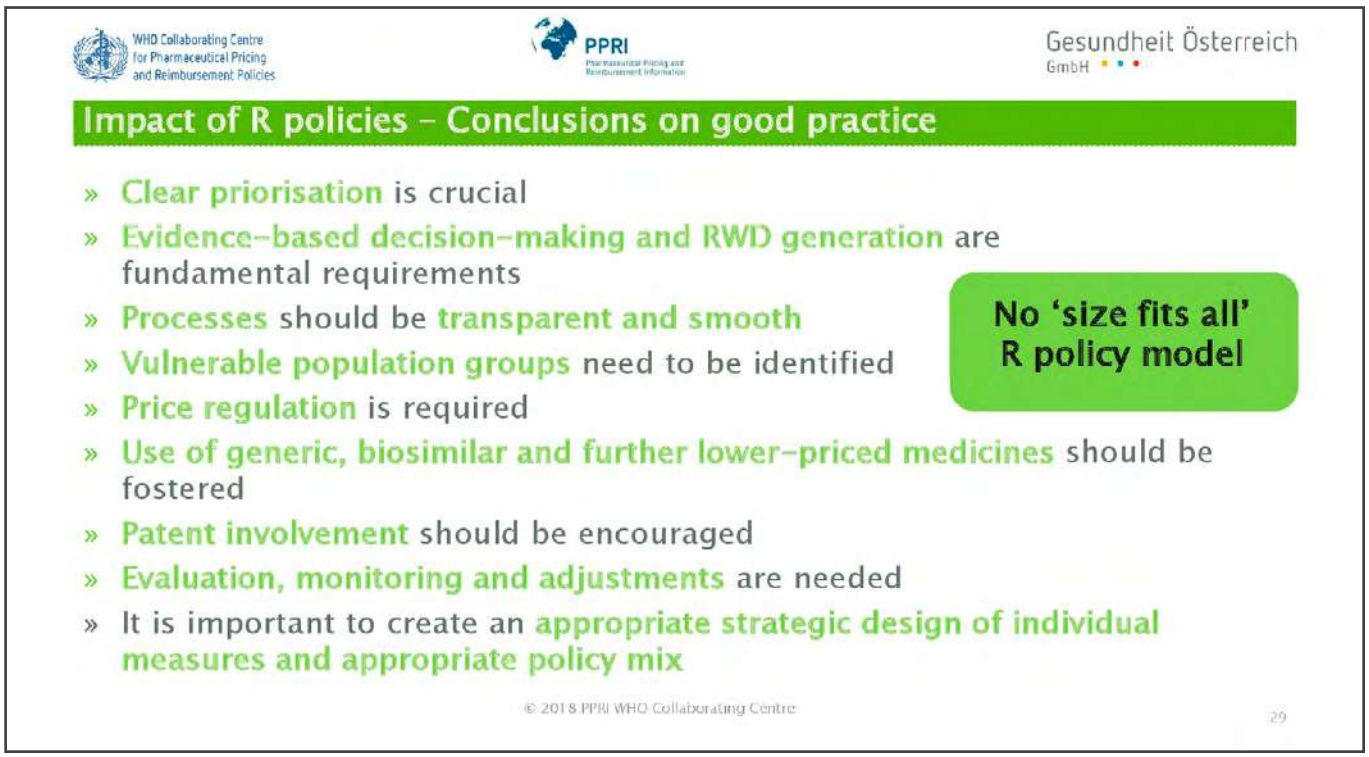
design of co-payment policies we can make an impact, but it is also a question of how high the price is in principle.



KEY FINDINGS

(Min. 00:53:35)

Having said this, I am now coming to my conclusions. Key findings were that increased financial investment is critical. Then we saw that several countries take different decisions regarding certain diseases, meaning that the co-payments vary depending on the medicine. The question is if there are socially disadvantaged people with a low income who are left behind by this policy? Different designs of reimbursement policies, not surprisingly, lead to different outcomes. And it is important to consider that it is not just about reimbursement. Reimbursement is one element but other policy options, like pricing, can also be supportive or hindering.



KEY FINDINGS

(Min. 00:53:28)

How shall reimbursement be done? It is clear that there is no one-size-fits-all reimbursement model but there are certain principles that are key. One is to have a clear prioritization. It is important to have evidence-based decision making. As I explained, HTA can help. Real-world data generation afterwards is fundamental because sometimes, especially with new medicines, you will see the value only afterwards in practice. Furthermore, processes have to be transparent and smooth and vulnerable groups should be identified in order to not just have a disease focus but to also protect certain groups. If there are co-payments can we make some exemptions? I have also already talked about the price regulation and the importance of generic policies and other lower priced medicines, patient involvement and monitoring and evaluation and adjustments are needed. Last but not least, it is important to create an appropriate strategic design of individual measures and to decide on the most appropriate policy mix.

QUESTIONS & ANSWERS

(Min. 00:55:30)

Question:

Sabine, under which circumstances would you recommend a negative list rather than a positive list?

Answer:

Well, I would say I could imagine having a combination. Negative lists can, for instance, work well for medicines that are of low therapeutic value or life style products when you are not sure if it can be demanded of the State to have them included. I would rather ask the question if there are certain types and categories of medicines that qualify for a negative list. But I would say it depends on the way you do it. I don't think that positive lists are better than negative lists. But I think depending on what you want to signal to your citizens, maybe the positive list sends a better signal meaning that we, as the public payer, are willing to include this medicine in the package. That is maybe the difference, but it is rather a technicality and a question of the message you want to send. But you could really think about having the positive list where you look at what WHO recommends and what is useful and important in our country context and for certain lifestyle products you can have a separate negative list.

Question:

Do you think that a cost-effective but unaffordable medicine might occur because the cost-effective threshold is too high?

Answer:

It is now difficult to find out if the question is also about us wanting to have thresholds communicated or not. Because I think technically yes it depends on the threshold I have. But I would also say that the fact that medicines are not affordable is really a result of the prices being simply too high. In recent years we have seen that they are really exploding. If we had discussed this fifteen years ago nobody would have imagined that medicines would reach such high prices. So the answer to the question is partially yes, but I would say that cost-effectiveness analysis is a technical issue and it includes the policy question where to set the threshold. And that is an issue. I would really say that the budget impact is something we have to consider for the future.

Maybe to add on to that, we have had some discussions in Europe to question if we still need cost-effectiveness analysis because we see that it doesn't work. But I think the important thing is to understand that it is a relevant tool but, of course, it is not the answer to policy questions. To really make the distinctions we need the tools but they have their limitations and are not the final policy decision.

Question:

Does the type of list a country has (positive, negative, combination) affects the level of prices?

Answer :

No, there is no evidence on that. But it would be difficult to have evidence on that because you have seen that we just have two countries in Europe where there are combined lists. It would also be difficult to look into it because nearly all countries have a positive list. But taking this question further, it is a matter of looking which are the factors influencing the price. I would not say that the policy of positive or negative lists has an impact but rather what the State or the public payer communicates regarding their ability and affordability to pay. So I would rather say that if you have certain criteria to define medicines which are of key importance that could maybe raise the price. And the other way, that is the off-patent market, the public payer is willing to supply certain medicines, but if there are different options that have the same effect, it will only pay for the generic or the lowest-priced medicine. If this is clearly communicated it can also have an impact on the price. I would say that these are the factors that are relevant.

Question:

Some countries negotiate prices as a condition to include medicines in the benefit package (e.g. UK or Austria). However, these negotiations are secret, so in many cases it is not possible to know what the true price is. Something similar happens with the managed entry agreements. How does this affect international reference pricing?

Answer:

That is a good question because that is the situation that we have now. And it is kind of a vicious circle because many countries use external price referencing since they need a starting point. They feel like at least they have this starting point together with cost-effectiveness and HTA etc. So first they use external price referencing. Everyone in Europe, in the meanwhile, knows that they are just calculating fake prices and nobody can pay for it. So all countries then reduce

the prices with managed entry agreements, as described. But the manufacturer insists that it is not communicated. Therefore, you signal something different to the other countries. I would say it is not just the fact that you have fake prices, it also has to do with the fact that global companies that know the situation of the real prices on all their markets. But the payers do not know. I am really very strongly arguing in favor of transparency also because, the way it is now, the bargaining power of the payers is weakened. So it is important to have transparency and the complete information. How can you have a good negotiation if you don't have the full information? We need that. That is my expert opinion. We need to find a way out of this vicious circle of secret negotiations. There is now a discussion in Europe but it is clearly something that can't be solved at the country level, where, for sure, we need collaborative efforts of more than one country.

Question:

Sabine, would you say that given a country has an efficient pricing scheme aligning cost with value, aiming for zero copayment system is a desirable policy?

Answer:

Personally, I think that lower co-payments are better. On the other hand, I believe that it still can be a fair system if you have a co-payment that is not hurting people. It is important to understand when it hurts people in a way that they will decide not to follow the prescription. Even if the ideal would be having access to all medicines and having no co-payments, I think it can still be a fair system. Also, co-payments are only one element. For instance, if a country takes the decision to include more medicines in the benefits package scheme but to ask for a co-payment that is bearable and does not hinder access, this could create more access than having a very small benefits scheme with few medicines which are free of charge. The important thing when having co-payments is to think them through and to think about the different population groups in order to have certain exemptions and reductions for those who need it.

CRITERIA

Regional Network on Explicit Priority Setting and Health Benefits Plans

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