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Chair

Mr. Bill Casey

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● (1200)

[*English*]

The Chair (Mr. Bill Casey (Cumberland—Colchester, Lib.)): We will open our meeting for our study on pharmacare.

We're very privileged today to have some testimony from the Netherlands and Sweden.

We very much appreciate your attending our meeting in Canada. I'm not sure what time of day it is there, but thank you very much for doing this. We're studying a national pharmacare program, and we're trying to avoid any pitfalls in our study if we can. I'm sure your testimony will help us.

First of all, we have Sofia Wallström, director general of the Dental and Pharmaceutical Benefits Agency of Sweden. We also have Aldo Golja, senior policy advisor on pricing and reimbursement of pharmaceuticals at the Dutch ministry of health.

I am going to start the questioning with Mr. Kang.

Mr. Darshan Singh Kang (Calgary Skyview, Lib.): Okay, but I thought we were going to hear some testimony.

The Chair: My mistake. I'm sorry, Mr. Kang.

We're going to invite opening statements from both witnesses, if you have opening statements to help us, for 10 minutes.

Ms. Sofia Wallström (Director General, Dental and Pharmaceutical Benefits Agency): Thank you very much, Mr. Chairman. As you said, my name is Sofia Wallström. I'm the director general of the Swedish Dental and Pharmaceutical Benefits Agency, the TLV. I want to thank you for the invitation to address the committee today, and I hope that our experiences can be beneficial to your work.

First, I will give you some background. Sweden is a medium-sized European country. The Swedish population reached 10 million in January this year. The population density is approximately 22 inhabitants per square kilometre. The population is geographically unevenly distributed. As in Canada, the inland and northern parts are scarcely populated, while the major urban areas are located along the coastline of the southern part of Sweden.

Swedish health care is a national health service system. Provision of health care is regulated by law, incorporates equal access to services based on need, and emphasizes a vision of equal health for all. The health care system provides coverage for all residents of Sweden, regardless of nationality. The Swedish system is highly decentralized, with three independent governmental levels: the national government, the regional county councils, and the local municipalities. They are all involved in health care.

The county councils have the main responsibility for providing health care, and there are 21 county councils that own and operate most of the health care facilities, such as hospitals and primary care centres. The 290 local municipalities are responsible for providing nursing home care, social services, and housing needs for the elderly.

The Swedish health care system is funded primarily by taxes, and the county councils and the municipalities have the right to levy taxes and determine tax rates. Principal health policy objectives and frameworks are determined at the national level, but the actual provision of services is done by the county councils and municipalities. The county councils are solely responsible for the funding of in-patient pharmaceutical expenditure. Costs for out-patient pharmaceuticals are formally financed by the county councils, but the government gives a special grant that covers the county councils' costs for out-patients' medicines.

Patients pay a limited part of the actual costs for visits and treatments. Patients pay a fee when visiting a health care service centre and when treated in a hospital. The maximum annual amount is 1,100 Swedish kronor, which is about 116 euro, and includes pharmaceutical treatments. In a separate system patients also pay a copayment of a maximum of 2,200 Swedish kronor, which is about 230 euro per year, for out-patient pharmaceuticals included in the pharmaceutical benefits scheme.

The Dental and Pharmaceutical Benefits Agency is the governmental agency responsible for pricing and reimbursement decisions on medicines used in out-patient care. The criteria for reimbursement are laid out in the Act on Pharmaceutical Benefits and can be summarized in three principles: the human value principle, the need and solidarity principle, and the cost-effectiveness principle. All of these criteria are to be considered and weighed together by the TLV. This means that, for new pharmaceuticals, TLV uses health and economic analyses as important bases for our decisions.

For products that have been on the market for some years but for which the patent has not expired or there is no generic substitution, Swedish prices a couple of years ago were very high. To deal with this, we had new legislation in 2013, and we now have an automatic price cut of 7.5% when a drug has been on the market for 15 years.

When it comes to the generic market, Sweden has obtained among the lowest prices in Europe for generic drugs. Generic substitutions for pharmaceuticals in pharmacies have been mandatory since 2002. For products with this kind of competition, pharmacies are obliged to offer the equivalent medicine with the lowest price per unit. Each month TLV informs which product in each package-sized group has the lowest retail price per unit, and it should be dispensed at pharmacies that month. The preferred product is appointed through a monthly auction at TLV, where the product that the pharmacies should offer is decided.

● (1205)

Competition between manufacturers has resulted in significant price reductions of these drugs. After three months, the price will fall by 40% on average, and after two years, the price should fall further, to 35% of the price before the competition arose. As the prices fall, volumes increase, which means that more patients get access to effective treatment. Also, financial resources are made available for other care, since the decrease in price is larger than the increase in volume.

I will now make a few comments on our work in the face of challenges with new pharmaceuticals. We see that quite a few of the new pharmaceuticals address high unmet medical needs and are judged to have a positive risk-benefit balance. However, they often come with a challenge. They are high priced, so it's hard to decide on price and reimbursement when many new drugs reach the market earlier in the development phases and have a larger uncertainty in their documentation. To meet these challenges, TLV has established a national platform for collaboration and dialogue with the pharma companies and the county councils. A managed entry agreement between the county councils and a pharmaceutical company may be one of several factors considered when TLV decides on price and reimbursement status. Risk sharing via managed entry agreements is an increasingly important tool to manage these uncertainties associated with scarce data.

Managed entry agreements between county councils and pharmaceutical companies also have potential as powerful tools to create competition and stimulate price dynamics within established therapeutic areas where, for various reasons, competition and price pressure have not arisen. One example is biologicals, where price competition rarely arises, despite the market entry of biosimilars. This work is now being implemented in practice and to date, agreements have been reached in several areas, including hepatitis C, heart failure, and cancer.

We're now moving forward both to institutionalize and expand the use of these risk-sharing models. We increase our efforts to include a proper plan for renewal of our decisions, based on follow-up and post-launch evidence generation. We aim to develop this further to allow early decisions, early access, and link it to continued development of knowledge.

In summary, the Swedish system provides universal health coverage mainly financed by taxes. Both in-patients and outpatients are covered. For outpatients, there is a copayment system with thresholds in place for pharmaceuticals with generic competitions. After patents expire, we have some of the lowest prices in Europe. For products older than 15 years, when there is no generic competition, there is an automatic price cut of 7.5%, which gives us a good precondition to face challenges, such as new, high-priced, innovative drugs or drugs aimed at rare diseases. Of course, our pricing decisions in our reimbursement work is being made more complex, as pharmaceuticals reach the market earlier with a larger uncertainty in their documentation. Our work and decisions are becoming more complex based on scarce data. Our value-based approach with health technology assessment is an important basis and we're now in the process of developing this further to meet these new challenges.

With this, I would like to conclude my intervention. Once again, thank you for this opportunity.

● (1210)

The Chair: Thank you very much for giving us a lot of information in a very short time. That's excellent.

We'll move to Mr. Golja, senior policy advisor on pricing reimbursement, from the Netherlands.

Mr. Aldo Golja (Senior Policy Advisor on Pricing and Reimbursement of Pharmaceuticals, Department of Pharmaceutical Affairs and Medical Technology, Dutch Ministry of Health, Welfare and Sports): Dear members of the Standing Committee on Health, thank you for the opportunity, on behalf of our Minister of Health, Edith Schippers, to present to you today. It's an honour to give you some insight into the Dutch system today for pricing and reimbursement of outpatient pharmaceuticals.

Our minister strongly values the voluntary collaboration among countries in the field of pharmaceuticals. In the international arena, the Netherlands has been a strong proponent of creating an environment that allows for long-term access to innovative drugs at affordable costs. Sharing knowledge and giving insight into policies among countries is a valuable part of ensuring access to pharmaceuticals. I hope that our exchange today will help you in facing challenges in your own pharmaceutical system, and might benefit Canadian patients.

As my colleague from Sweden did, I will try to give you a short insight into the Dutch pharmaceutical system.

The Netherlands is a slightly larger country than Sweden. We have approximately 17 million inhabitants. We basically have a private health insurance system, with the goal of providing health insurance and access for everyone equally. It's made up of a compulsory insurance, with a compulsory acceptance of patients or civilians, without differentiated premiums.

The characteristics are that it's an entitlement-based system, where the minimum standard of care is legally determined by the government. Basic health coverage is identical for all insurance companies, so they all have to provide the same basic insurance. There is a broad benefits package. For this benefits package, the maximum overall out-of-pocket payment is about 385 euro a year, which amounts to approximately $574 Canadian. This also includes copayments for pharmaceuticals.

In essence, there is a marketplace that consists of basically four large insurance companies and some smaller companies, but the four large insurance companies control approximately 90% of the market. The premiums are set by the insurance companies. The competition among those insurance companies is meant to keep the premiums at an affordable level.

The health providers themselves are mostly privatized, but are largely not-for-profit organizations, especially when it comes to hospitals. In the outpatient sector, of course, the general practitioners are private health providers.

If you look at the system, you will see that it's a regulated competition. This means that the insured, no matter their background, their income, or their health, are free to choose their insurer; and they have the option to change every year. Insurers, in turn, compete for the insured on a premium, quality, and service level. Health care providers compete for contracts with insurers on price and quality of care.

When you look at the outpatient sector or the life cycle of pharmaceutical products, you see that in a monopoly situation, where products are first in class, of course there are limited market forces in place. They slowly start to appear when a competition arises with single-source products that have therapeutic-equal benefits, but they still do not have the same active substances.

Once generics start entering the market, more competition is possible. This also defines the essence of the Dutch pharmaceutical system. When products enter the market, there is an external reference price that's set, which goes for all drugs that come to market. It is an average price of those in Belgium, the U.K., Germany, and France. The external reference price is recalculated every six months.

There is a positive list for the outpatient drugs, which means that before a drug is reimbursed in the national health system, a full HTA, health technology assessment, needs to be done. This consists of the assessment of the therapeutic benefit, plus of the pharmacoeconomics, which basically means that there is a cost-effectiveness assessment done, as well.

This assessment is performed by the Dutch health institute, which is a government organization, but an independent scientific organization. Based on the advice this institute gives, the minister approves the reimbursement for each drug.

● (1215)

Reimbursement is based on the therapeutic effects. When products are being reimbursed, and once there are products of equal therapeutic benefit, there are clusters made of comparable products. This means that different active substances with comparable therapeutic effects basically have the same maximum reimbursement in a cluster. Once generics start appearing into the market, these are also put into the same cluster as all the products that have the same therapeutic benefit.

The reimbursement of products from these clusters is based on the first product that comes to market. This is essentially the external reference price of that product. The costs exceeding the reimbursement limit have to be covered by the patient. This means that if the price of a drug is higher than the limit set for this specific cluster of products, the additional fee has to be paid by the patient. This happens relatively rarely. It's also because at least one product has to be without additional copayment. In each cluster, there should be one that's without copayment, so if there is a price rise, then it will have to be covered by the reimbursement system.

When you look at the life cycle of the product, as I said, there's an external reference price to begin with. You could say this is high government interference. Then once generics shift into place, there is a functioning marketplace in which the insurance companies get to play their parts, which actually means that the insurance companies start tendering for their generic products. The prescribers have to prescribe an INN. They contract with insurance companies on the care they deliver, and they receive incentives for appropriate use and for the prescription of generics when possible. That allows the insurance companies to tender for generic products once they're on the market and to tender them for the lowest price possible.

Pharmacies, in turn, are also contracted by the insurance company. They receive a tariff for handing over prescriptions, and they receive margins on products. For generics, that means there is a contracted margin they receive from the insurance company for providing the specific generic that each insurance company has agreements with. For speciality drugs, that depends on the product-specific rebates. They also receive contracted fees for additional service when it comes to pharmaceutical care.

If you look at the effect of the insurance companies' ability to tender—with each of the four companies tendering the generic products themself—you will see that the effect has been relatively drastic.

In my a presentation there's a slide that some might say I stole from the Swedish TLV, showing that Sweden, with a relatively centralized system of purchasing and reimbursement of drugs, has similar prices of generics as the Netherlands. We have a system that functions in the marketplace and we have the same prices. It's just that it functions in a more centralized way. This is interesting, I think, to look at. For the generic market, for instance, if you look at the 2016 prescriptions, 74.1% of prescriptions in the total market of prescriptions in the Netherlands are in the outpatient generics sector, and 25.9% of specialty drugs. If you look at the expenditures, generics take up 16.8% of expenditures in the outpatient sector, and specialty drugs still take up 83.2%. So generics are 74.1% of all prescriptions versus costing 16.8% of the total. The total expenditures of outpatients, by the way, were 4.7 billion euro over the last year.

We have relatively high substitution rate of 96%, which, as I think my Swedish colleague already mentioned, means that as soon as a product is off patent and as soon as insurance companies contract these generic products from the companies, patients are switched to the generic really fast and in large numbers. As soon as a generic comes to market, you can see the shift really taking place.

● (1220)

Now, there will be dilemmas in the future. One was already mentioned. That's the biosimilar case, where there seems to be no competition in biosimilars, or at least very limited competition, when biosimilars come to market.

We have a different way of dealing with this cluster of products. We saw that our outpatient system couldn't provide for lower prices. We transferred them to the in-patient sector. Hospitals in general are responsible now for the cost of biosimilars, which means that insurance companies contract hospitals, and they also contract the prescription of biologics or biosimilars. Now that there is a stimulus for the hospitals to reach lower prices, to use their volume, to use the prescriber, and to make good agreements with their in-house doctors who prescribe these drugs, we see that there is a price fall happening. However, the price fall is not as high as it is in Sweden. I think in Sweden their price cuts are approximately 90% of the original price when it comes to biosimilars. At this point we're at 50%, but we're decreasing. It seems to be promising.

With regard to the new drugs, when it comes to the new outpatient but also in-patient drugs that come to market with increased prices, the Netherlands has had a system in place for several years in which on a national level—it's not the insurance companies, but on a national level—there is a managed entry process for specific drugs that have large budgetary impacts, that entail high costs for patients, or that have a high uncertainty. Before the products are entered into the insurance schemes, before they're up for reimbursement, the ministry itself takes up a managed entry route with the company. Those are selected products. They're not the full range, but there are five to ten products per year, you could say, that on a national level we tender on.

The idea or thought behind this is that the marketplace can use a lot of the market forces to reach lower prices or to come to good price agreements, but when it comes to these monopoly products that have high budgetary impacts and often large benefits for patients, it's really hard for insurance companies to achieve lower prices. The only way to do that is to take up these products and reach market entry agreements on a national level.

So we have a different system from the Swedish. It's more decentralized, relies on market stimuli and market forces, and tries to create these forces when and where possible. That leads to interesting results.

Thank you.

● (1225)

The Chair: Thank you very much.

Now we will turn to questions.

We'll start with Mr. Kang for a seven-minute round.

Mr. Darshan Singh Kang: Thank you, Mr. Chair.

I'd like to thank you both for your presentations. I think the more we hear, the more complicated things get. Certainly you've given us a different perspective on this. I have lots of questions for both of you.

OECD countries face common challenges in addressing new high-cost specialty drugs used in the treatment of cancer, hepatitis C, pulmonary hypertension, multiple sclerosis, and rare diseases. In a number of countries, these drugs are not affordable or accessible to patients who need them. Conversely, sometimes high-cost medicines do not always deliver high health outcomes.

How are the challenges associated with high-cost specialty drugs addressed in your country? What best practices in this area, from either your country or elsewhere, could Canada consider using or adopting?

Ms. Sofia Wallström: In Sweden, we have the value-based approach, which means that the TLV uses health technology assessment as an important tool on which to base our decisions. When we assess a new drug, we take into account both therapeutic effects and, of course, the cost of using this drug in clinical practice. We also take into account the severity of the disease and if there are any available alternatives already.

The development, where the new pharmaceuticals come to market with more uncertain data, is really a challenge when it comes to making these assessments in early phases. That's why we have developed this national platform together with the pharma companies and the county councils. Within these so-called three-party negotiations, we develop tools in order to make an early assessment, reimburse the product to a small patient group, and link that to a data collection, real-world data, as a complement to RCTs, randomized control trials.

Our ambition, with this real-world data as a basis, is to make a follow-up, and hopefully the drug delivers as much as it promises and we can take that data as a basis for expanding the patient population and making the product available and reimbursed for a larger patient group. I wouldn't say that we have solved this problem, but I think we have started work that tries to meet these challenges in the collaborative framework.

Mr. Darshan Singh Kang: You are saying that you are trying to have a blanket approach with your data for all the patients, the same drug—

Ms. Sofia Wallström: The follow-up in early phases and in small patient groups in clinical practice, within these real-world data pilots that we have launched this year, is absolutely key.

Mr. Darshan Singh Kang: Thank you.

You talked about in-patients and out-patients. When the patient is in the hospital, they are fully covered, there's no copayment, and when they're out of the hospital there's a copayment.

Is that how it works?

● (1230)

Ms. Sofia Wallström: Yes, that's how it works.

Mr. Darshan Singh Kang: Okay.

Mr. Golja, did you want to add something to that?

Mr. Aldo Golja: Yes.

I think in our system, we do have—

Mr. Darshan Singh Kang: Be brief, please, as I have more questions.

Mr. Aldo Golja: Yes, okay.

When the new products come to market and when they're up for reimbursements, especially in the out-patient sector, we rely on the HTA assessment. We look at the cost-effectiveness. It's not an absolute criterion, but it's an important measure to use, for instance, with products that have a large budgetary impact, including oncology products coming to markets in the in-patient sector.

We'll use the outcome of the HTA to engage in negotiations with pharmaceutical companies to reach managed entry agreements. When there is a clear view of therapeutic benefit and of the cost-effectiveness, that means there's a financial arrangement that's being met, with additional data collection if necessary.

It especially helps if we engage with the prescribers when it comes to appropriate use. As long as products come to market, as long as they're used, if there is benefit for patients, then the patient should have access to these products. We should also be very aware from the start that these products are being used in the way they should be used, and to assume that their therapeutic effect in real life shows that there is an added benefit compared to other products, and that prescribers act on that as soon as possible.

This is one of the important things that we are putting into the system now: we're engaging with prescribers.

Mr. Darshan Singh Kang: Thank you, sir.

You have your formulary. How many drugs are covered under your drug formulary: 100, 50, 70, 60?

Mr. Aldo Golja: I don't have the figures on how many drugs are being reimbursed, but basically each drug that has a therapeutic benefit is reimbursed.

Mr. Darshan Singh Kang: Are there 50 under your formulary? How many drugs are covered?

Mr. Aldo Golja: I think there are thousands covered, or something like that, so it's a wide array.

The Chair: Ms. Harder.

Ms. Rachael Harder (Lethbridge, CPC): Thank you so much for giving us your time today and allowing us to enter into a discussion with you so that we can learn from you.

My first question is for Mr. Golja.

You're saying that 75% of pharmaceutical costs cover only 25% of the prescriptions used in your country. Is that true? Am I hearing you correctly?

Mr. Aldo Golja: What I said was that, of the total number of prescriptions in the outpatient sector, 74% of the products that are being prescribed to patients are generic, and that they take up 16.8% of the total cost in the outpatient sector.

Ms. Rachael Harder: All right. Thank you.

Now while I have you, I'll just ask you another question. What is the population of the Netherlands?

Mr. Aldo Golja: It is 17 million.

Ms. Rachael Harder: It's 17 million. Okay.

You've talked about the fact that there are flat rate premiums, that there are small deductibles, and that there is also taxation associated with being able to provide a universal pharmaceutical program. What is the income tax amount that individuals are paying?

Mr. Aldo Golja: Do you mean in the Netherlands?

Ms. Rachael Harder: The flat rate premium is equivalent to $574 Canadian dollars, if I understand correctly. On top of that, individuals are paying a small deductible, and then on top of that, they're paying out of their income tax.

What is the amount of income tax that is going toward this program?

Mr. Aldo Golja: The Dutch system is a bit different. There is a nominal premium that the insured pay towards their health insurance. I've counted it, and it depends a little bit on the insurance company, but I think it's about 110 euro per month. This is the monthly nominal fee that the insured pay to their insurance company. On top of that, for those with lower income, there is a subsidy based on their average income.

In the back end of the system, there are some tax funds that go into this system, but they're not directly derived from the actual insured person.

Basically, everyone pays 110 euro, and they have a maximum copayment of $574 Canadian dollars per year, you can say, if they take health care.

● (1235)

Ms. Rachael Harder: Sorry, with all due respect, that income tax dollar does come directly from the benefactor; hence, it's income tax.

What is the amount, then, that the government is putting toward this program? What is the annual expenditure?

Mr. Aldo Golja: I don't have right here the actual expenditure figure towards health insurance. It's not actually the pharmaceutical program that is specifically funded. It's a general funding of the national health insurance scheme that's being funded.

However, I can get that figure if you want it.

Ms. Rachael Harder: Yes, that would be helpful. Thank you.

I'll now come to Ms. Wallström.

Do you know what the cost is? What cost is the government fronting in order to follow through on this program?

Ms. Sofia Wallström: For the outpatients pharmaceutical benefits scheme?

Ms. Rachael Harder: Yes.

Ms. Sofia Wallström: That would be about 25 billion Swedish krona per year, which I think is about 2.5 billion euro per year.

Ms. Rachael Harder: Okay, so it's 2.5 billion euro.

What is the population of your country?

Ms. Sofia Wallström: It is 10 million.

Ms. Rachael Harder: It is 10 million. All right.

I'm sorry, I don't know enough about the history. At what point did you move from whatever your former system was into a more universal pharmacare program, or has it always been?

Ms. Sofia Wallström: It has been so for quite some time. My agency was formed in 2002. Even before that, we had a universal pharmacare program in Sweden, but not with this kind of elaborated pricing and reimbursement decisions. It was more of an automatic reimbursement when new products came to market. Of course, in the seventies and the eighties that functioned pretty well, but in the nineties there was a financial crisis in Sweden. Several of the systems were re-regulated, and more cost control aspects were built into these systems.

Ms. Rachael Harder: Thank you.

Can you explain to me a little bit about how you go about approving new drugs for market? Who approves the new drugs that come into the formulary?

Ms. Sofia Wallström: The regulatory work in Europe is harmonized, so it's the same for all the EU countries. There is a European agency, the EMA, that approves the drugs. That is a joint regulation for all countries.

Ms. Rachael Harder: Sorry, I should clarify. I meant with regard to the formulary, in other words, the drugs you would cover under the plan.

Ms. Sofia Wallström: Of course. When the product has come to market, it is the TLV that decides the price and the reimbursement within the pharmaceutical benefits scheme. If it's an in-patient drug, it is the 21 county councils that have a tender procedure to decide on the price and usage of in-patient drugs.

Ms. Rachael Harder: Perfect. Thank you very much.

Mr. Golja, I would ask you the same question.

Can you help me understand how you decide which drugs are going to be a part of the formulary and which drugs are going to be covered for patients?

Mr. Aldo Golja: The National Health Care Institute of the Netherlands is more or less a scientific body that does the health technology assessment. It basically advises the minister on adding certain drugs to the formulary and the reimbursement. They assess the drug. They also do a cost-effective analysis based on the price the company provides, and they advise the minister on that. In the end, the minister decides what the maximum reimbursement will be for out-patient drugs.

● (1240)

Ms. Rachael Harder: Do you...?

The Chair: Your time is up.

Ms. Rachael Harder: Oh, it's not, actually.

The Chair: It is according to our clock.

Mr. Davies.

Mr. Don Davies (Vancouver Kingsway, NDP): Thank you, Mr. Chair.

Mr. Golja and Ms. Wallström, thank you so much for being with us here today.

As you are probably aware, one of the goals of our committee study is to explore how we can provide universal pharmaceutical coverage for Canadians, which we don't have now.

My first question is a simple one, and it may be obvious.

Maybe we'll start with you, Ms. Wallström. Is one of the goals of your system to provide universal coverage for all Swedes?

Ms. Sofia Wallström: Yes, I would say it is.

Mr. Don Davies: Mr. Golja, is that one of the goals of your system?

Mr. Aldo Golja: Yes, it is.

Mr. Don Davies: Okay.

Ironically, it has been estimated in Canada, depending on who you talk to, that we pay between the second highest and the fourth highest drug prices in the world, while at the same time not providing universal coverage.

I would like to ask each of you where each of your respective countries fit in terms of, say, the world, or perhaps the EU or the OECD, in terms of drug costs.

Ms. Wallström, maybe I'll start with you.

Ms. Sofia Wallström: We have a relatively high expenditure on health care costs in Sweden, but we also have a good ratio between the quality of the medical results and the resources we put in.

When it comes to the pharmaceutical part of the health care spending, it's average on a European level. When it comes to prices, we have slightly over-average prices within the European Union. When it comes to products on patent, those without competition, and when it comes to products off patent, those with generic competition, together with the Netherlands we have among the lowest prices in Europe. Overall, I would say we're average.

Mr. Don Davies: Thank you.

Mr. Golja.

Mr. Aldo Golja: I would say the same. We're slightly above average when it comes to total expenditure on health care. In the European Union when it comes the monopoly products, looking at the external reference price of these products, I would say that our prices are average within the European Union. Also, as Ms. Wallström said, our generic prices are among the lowest in Europe.

Mr. Don Davies: Now I'm going to try to delve into why that is.

Maybe I'll start with you, Mr. Golja. It sounds as though you're managing to provide universal coverage for your citizens and you are keeping control of costs pretty well. What do you attribute that to? How are you able to do it? What is the factor that is accounting for that success?

Mr. Aldo Golja: I think it's a combination of the responsibilities and the drivers in the system. You could say that trying to regulate the market to have obligatory insurance with obligations for insurance companies but also incentives for them to keep their premiums at an affordable level while also providing for the care of their patients drives them to find the lowest price in the market.

As a result of prescribers' being contracted, when it comes to the prescription of generics according to set guidelines, the parties involved all have an incentive and benefits to keep the financial burden on the system as low as possible. It's a balance—the market balance, you could say.

Mr. Don Davies: Thank you.

Ms. Wallström, I'll put the same question to you.

Ms. Sofia Wallström: I would say that the efficient system for generic competition is an important basis. It creates headroom for innovation, and that leaves us in a good place when it comes to our relatively high, I would say, willingness to pay for new pharmaceuticals that bring added value. Having the value-based approach and trying to develop our decisions on our follow-ups in such a way as to pay for performance or pay for results and link that to our developed real world data work has also, I think, helped.

Also, as my colleague said, it's the combination of both, and it's also due to our collaborative framework for dialogues with the county councils and the pharma companies.

● (1245)

Mr. Don Davies: One fear we hear expressed about Canada's moving towards a universal system is this: some people warn—I think primarily industry representatives—that Canadians may face a lack of choice in getting the drugs they really want or need.

Do you have that experience in your countries, in Sweden and the Netherlands? Are you able to make sure that your patients get the actual medication they need and want within a universal system?

Ms. Wallstrom, you may go first.

Ms. Sofia Wallström: In the Swedish system, all doctors are working for the county councils. There are no doctors who are totally private. There is thus a whole system that links one to another when it comes to choice and access.

I would say that in the few situations we experience in which we haven't been able to reach reimbursement status for new important pharmaceuticals, it has been possible for the Swedish system to handle the situation. So far it has also been possible for the political system to stand up for doing so. This also means that these are exceptions from the usual situation, such that it's possible for us to anchor our decisions with the prescribers and with the rest of the county councils and the health care system.

Mr. Don Davies: Thank you.

Please give us a short answer, Mr. Golja.

Mr. Aldo Golja: I agree with what was said. In our system we have the freedom of choice for the prescriber; there are thus plenty of options for the prescriber to prescribe whatever he or she feels is necessary for the patient.

It's not as if there have been companies leaving the markets, with the system freed up with generics and given our ability to tender and various insurance companies participating in the tender. Even in the generic space, several providers are engaging in competition.

When it comes to new products, the Netherlands seems to be relatively early in the launch sequences of companies, and we haven't yet had shortages of new products not yet introduced into the Netherlands.

I don't feel that patients are missing out on products they should have had.

The Chair: The time is up.

Ms. Sidhu, you have seven minutes.

Ms. Sonia Sidhu (Brampton South, Lib.): Thank you, Chair.

Thank you both, Ms. Wallström and Mr. Golja, for joining us today.

Ms. Wallström, first, could you please tell us whether bulk purchasing of medicines is a part of your policy, and, if so, can you please explain what difference that makes to the cost of prescription medications that individuals face?

Ms. Sofia Wallström: You mean that if the volume is higher, the prices are low? Well, not specifically, but, of course, the health technology assessment is based on a model in which a larger patient population often gives a larger value. In that sense, the price should be lower. But in our decision-making, it's more of an implicit factor, I would say, with the exception of the generics, of course, which involve another kind of decision-making.

Ms. Sonia Sidhu: To determine which medications will be covered by your health care system, could you please explain how you protect these formulary decisions from political perspectives? It is not affected by your political perspective? It's not affected by the system?

● (1250)

Ms. Sofia Wallström: I really beg your pardon, but I need to understand better what—

Ms. Sonia Sidhu: Can you explain how you protect these formulary decision to purchase the medications? Are the decisions not affected by the political system?

Ms. Sofia Wallström: It's the TLV, which is an independent agency, that makes the decisions, and our decision-making is based on legislation and the Act on Pharmaceutical Benefits, and, of course, I am appointed by the government, but I'm not political. That's more or less the Swedish system for a major part of the decision-making like this, and we are independent when it comes to our relationship with the ministry and the government.

Ms. Sonia Sidhu: I understand that even with the drug benefit scheme, individuals face copayment for their medications, which causes some people to skip doses or not refill their prescriptions. We have that problem in Canada, where 20% of people sometimes cannot afford medications. Can you comment on whether you have seen a decrease in this kind of activity since implementing the drug benefit scheme?

Ms. Sofia Wallström: There are a number of patients at this point who for economic reasons do not get their medicines, and the government has made some reforms targeted to certain patient groups, for example, contraceptives for young women. A recent example is all the pharmaceuticals within the pharmaceutical benefits scheme for children and young adults up to 18, which are with no copayments at all. So the government has made some changes in the high-cost thresholds in order to avoid some of these problems.

Ms. Sonia Sidhu: Mr. Golja, could you please explain the different classifications of prescription drugs and how the classification impacts how much will be reimbursed? Can you explain those?

Mr. Aldo Golja: What do you mean exactly by the different classes?

Ms. Sonia Sidhu: Could you explain the different classifications of prescription drugs and how these classifications impact how much will be reimbursed?

Mr. Aldo Golja: Do you mean the clustering of the products?

Ms. Sonia Sidhu: Yes.

Mr. Aldo Golja: Okay. By having clusters of products that have equal benefit, with the health technology assessment showing that there is equal therapeutic benefit between, for instance, two active substances, the person will receive the maximum reimbursement in this cluster. The prescriber has the freedom to prescribe either one of those products. But when there is a copayment of one product—let's say, the maximum price is $100, and there is one product that has a maximum price of $100, and one that goes above that, so $120, for instance—then you will often see a tendency for prescribers to prescribe the drug that has no copayments, that has no additional contribution by the patient. You do see some movement towards that.

When there is a generic product in that market, basically the generic has the same maximum reimbursement level as the originator. But because it's a generic, as soon as there is competition in generic markets, and we see for the majority of products there is competition, we will see that price drop really low because the insurance company actually determines what it will pay for this product. Based on the expected volume within the insured population, often the larger insurance companies, with a larger patient population of sometimes one or two million, will be able to negotiate a lower price for a specific generic supplier. Then, because it's ascribed an INN, 96% of the population almost immediately goes to the generic product that's been handed over.

Is that a sufficient answer to your question?

● (1255)

Ms. Sonia Sidhu: Yes, thank you.

The Chair: Okay, thanks very much.

Now we'll go to our five-minute round, starting with Dr. Carrie.

Mr. Colin Carrie (Oshawa, CPC): Thank you very much, Mr. Chair.

I want to thank the witnesses for being here and helping us with our issues with pharmacare programs.

I realize, too, that in every country things pretty much evolved a little differently and that you've come up with your own solutions. But, Mr. Golja, looking at your system in the Netherlands, I see that in the 1990s you basically had a system similar to Canada's, where you had, really, public and private health insurance plans. Then you began to unite them both into what you're calling this managed competition model, in which every person is basically obliged, if they can, from their own pocket, to buy private insurance, but the benefits would be specified by law. That's been going on since 2006. Because that seems to be similar to what Canada had, I wonder if you could enlighten us on what challenges the Netherlands faced in transforming its health insurance system from this mixed public/private health insurance model into a single-managed competition model.

Mr. Aldo Golja: There were many challenges, we could say. I specialize a bit more in the pharmaceutical area, but in general you could say that one of the big challenges after 2006 has been for the different stakeholders to grow into their roles. For instance, insurance companies came from a non-competitive environment, where they had more or less a set population of insured persons. They were not used to purchasing or contracting care. They had to get used to this role in which they had to find ways to contract care efficiently, but also make sure that the quality of care was up to standard and that the insured patients were also happy with the care they received. This has been a long process. Over the past years, if you look at the interaction between prescribers on one hand, and the insurance companies on the other hand, and also the pharma companies, you see that finding the right optimum between costs and care at the same time is something that has taken a long time to evolve. Still you see challenges within the insurance companies, especially when it comes to insuring the best possible care. When you talk about appropriate use, for instance, or when you talk about cancer care, you want to make sure that it's the biggest bang for your buck, as the Americans say. Trying to find that scientific or unbiased way of contracting that, I think, is one of the most important challenges at this point.

Mr. Colin Carrie: We've had a number of witnesses who would like Canada to move to the single-payer public health care system and more of a monopoly type of system. You guys picked this competitive model. Could you explain why the managed competition model was chosen over the single public health insurance system? In your view, what are the advantages and disadvantages of these two approaches?

I see you're smiling. This is a fun question.

Mr. Aldo Golja: Yes, that's a very interesting question.

Sometimes things evolve based on political decisions or motivations, so that might also have an effect.

We came from a situation where there was more or less a clear distinction between the insurance companies. They were more regionally organized. They were not self-sufficient but they were relatively self-standing organizations. They were non-governmental organizations, so the thought behind that was to hand them the tools to create a system that was a non-centralized system, or a non-monopoly system, to create sort of a market system, because of the position of the insurance companies and the care providers that were already there. The mechanism was already there, and it had to be regulated in the right way....

Mr. Colin Carrie: All right, I'd just like to finish off by saying I'm very surprised that politics took on such an important role over there. That would never happen here.

Thank you.

● (1300)

The Chair: Thank you very much.

Now we'll go to Mr. Oliver.

Mr. John Oliver (Oakville, Lib.): Thank you very much.

Thank you for your presentations.

Both countries are using a copay model, either a first dollar and then a copay, or a straight copay. I'm wondering if there was a public policy you were pursuing with the copay decision, or is it simply affordability and trying to take those front-end dollars off the government's cost?

Second, we've been cautioned against using copay if we were looking at a model, because of income disparity and the belief that low-income people would have greater difficulty accessing it and would not fill prescriptions because of affordability in that case.

So, first, was it just a matter of affordability, or why do you have copay? And second, have either of you seen barriers for the poorer people in your economy?

Ms. Sofia Wallström: I would say that in Sweden we have had this copayment system for a very long time, so I don't think I can really answer what the motives were in the beginning. Of course, the thresholds have been changed over time, so it's higher now than it was in the beginning, naturally.

I would say it's mainly a political ambition of affordability and equal access, but I would also say that it is clearly stated that it shouldn't be zero. It should be a copayment and it should be somewhat substantial, and that is because we can see that patients have a tendency to take out too much of the medicine if it's at no cost, and it's not used properly, so there are problems with compliance and medicines being thrown away. That's also a problem for the environment and so on.

Mr. John Oliver: What is the Dutch experience?

Mr. Aldo Golja: Traditionally we've had a system with relatively low copayments. This is our tradition. I believe some time ago there was an experiment with copayments specifically for drugs, but this was withdrawn after it was shown that many people were opposed to that, so in the new system, effective as of 2006, there is general copayment of 385 euro, which I was talking about earlier. This basically goes for all care that people take up in a year, except GP care. Basically everyone is free to go to a GP. They are the gatekeepers in our system to make sure that, when people need care, they can go, so there is no threshold to meet—

Mr. John Oliver: Neither of you has seen inequitable access because of affordability then? There has been no evidence of the poorest in your economy having difficulty accessing pharmaceuticals?

Ms. Sofia Wallström: I would say the Swedish system's threshold is fairly low, and very low compared to other countries'—

Mr. John Oliver: So you're not seeing an access problem, then?

Ms. Sofia Wallström: For specific groups, there probably is a kind of access problem. As for how big it is and the best way to solve this kind of problem—whether is it specifically related to access to pharmaceuticals or a more general problem—I would say that it's a political question. The reforms that I mentioned earlier when it comes to children, and young women when it comes to contraceptives, is one kind of response by the political system in adjusting the thresholds.

Mr. John Oliver: Okay. Thank you.

The last question I had was for the Dutch. What's the value add of the insurance companies? If, on the pharmaceutical side, the doctor writes a prescription and the patient fills it, what's the value add of the insurance company in that model?

Mr. Aldo Golja: Basically, if an insurance company is able to maintain low expenditures on pharmaceuticals, they can spend more of the premiums toward other forms of care.

Mr. John Oliver: So the insurance companies negotiate the price of the pharmaceuticals?

● (1305)

Mr. Aldo Golja: For the generics, especially, yes. It's to a limited extent when it comes to single-source products that are of equal benefit.

Mr. John Oliver: Okay.

The Chair: Thank you very much.

Mr. Webber.

Mr. Len Webber (Calgary Confederation, CPC): Thank you, Mr. Chair, and thank you both for being here today.

I want to direct my first question to Ms. Wallström and talk about the out-of-pocket copayments again. I know that Ms. Sidhu brought up some questions there.

We've got about 10% of Canadians who do skip their medications because of the fact they just basically can't afford to purchase them. According to our notes from the Library of Parliament, about 6% of Swedes are doing the same thing. I'm just curious to know about these out-of-pocket expenses. Have there been increases or decreases in the overall cap on the out-of-pocket expenses for prescription pharmaceuticals over time? If so, what accounts for the changes?

Ms. Sofia Wallström: The threshold has been in place for quite some years. I don't have the figures right now, but I would say that for maybe 10 years the threshold did not change at all. Then a couple of years ago, the government decided to increase the threshold so that it's now around 230 euro per year. I would say that the government's motives for that were that it was still at a fairly low level and there was a need to adjust to developments in general.

We have had different governments in the last mandate periods, and the new government, which is more left-wing, has decided on these reforms to lower the threshold for certain patient groups. There is no, I would say, political debate in Sweden as of now targeted toward the pharmaceutical benefit scheme and the copayment by patients in that direction. There are other debates when it comes to dental care, for example, as patients in Sweden pay much more for that. The political focus is more concerned with those areas.

Mr. Len Webber: I see. Thank you.

I know that my colleague Colin Carrie had a couple more questions, so I'm going to pass the rest of my time to him.

Go ahead, Doctor.

Mr. Colin Carrie: Thank you very much.

Getting back to Mr. Golja, about moving towards this managed competition model, are there any lessons that were learned from the Dutch when you guys were looking at reforming the health insurance system that Canada should consider if we're going to move to this type of coverage? Could you maybe give us some advice on what steps we could take to facilitate this? It seems you've been through this already.

Mr. Aldo Golja: Unfortunately, this is not really my expertise. So, unfortunately, it would be very difficult to explain what happened in 2006. I don't really have very specific lessons to hand over.

I would definitely say that if you were to engage in such a system, you should make sure that you find the right balance between the parties and that you keep in touch with whether or not your regulations and the market are still functioning. I think that's an important factor. I'm saying “market”, but it's a controlled system, of course, instead of an actual market.

One example I can give you, if you will allow me, is that of the biosimilars, where we saw that when it came to these out-patient drugs—or at least they are considered external drugs—when the biosimilars came to market, there was virtually no competition in the system at first. By analyzing the problem and seeing that apparently within the system the different parties could reach lower prices, we had to find a way of recreating the balance, which we found by putting it into the intramural sector and allowing for the total budget to be negotiated within the hospital sector.

So, we're really trying to fine-tune that and also allow for mechanisms that shave off the negative effects, you could say—because we were talking about copayments just now. Of course, in one of the debates, especially in our last elections a few weeks ago, many parties said that the yearly copayments should be lowered.

So there is debate about, for instance, vulnerable parties who take up a lot of care and who automatically make their copayments immediately—and that's an actual payment they have to make every year. Then, additionally, there are all sorts of different extra expenditures that they have in their daily lives. I think allowing for mechanisms to mitigate these negative effects is one of the important elements of our system....

● (1310)

Mr. Colin Carrie: Thank you.

The Chair: Dr. Eyolfson.

Mr. Doug Eyolfson (Charleswood—St. James—Assiniboia—Headingley, Lib.): Thank you so much. It was a pleasure listening to both of you. The luck of the draw is that a lot of the questions I had lined up were asked by other members of the panel.

This may have been answered, and forgive me if it has been covered.

Ms. Wallström and then Mr. Golja, you talked about how you have the copayments, and I know you said there are certain drugs that are not subject to copayments, or certain groups, children and that sort of thing. What is the provision for people who are destitute to the point of not being able to make any sort of copayment? Is there a provision to make sure that these people get covered?

Ms. Sofia Wallström: In Sweden there is, and there is a social security system that allows grants for these patients. Often it's more than just the pharmaceutical copayment that they need help with, so that is part of it.

Mr. Doug Eyolfson: Thank you.

Mr. Golja.

Mr. Aldo Golja: It's the same here. There is a normal fee that you pay, which everyone has to pay every month, but at the same time there is an income-related subsidy for those with lower incomes, so that the monthly premiums go down, but then there is still the copayment issue.

Mr. Doug Eyolfson: Sure.

Mr. Aldo Golja: For these patients or these people who are not able to pay that, there are special provisions. For instance, there are municipalities that are reinsuring the copayments for a very limited group. There are different mechanisms in place.

Mr. Doug Eyolfson: Okay. Would both of you agree that basically no one is left behind because of their inability to pay? Would that be a fair generalization?

Ms. Sofia Wallström: On a general level, I think that is fair to say, but, of course, there are situations in which people tend to get into problems anyway. But on a general plane, I would say yes.

Mr. Doug Eyolfson: All right.

Mr. Aldo Golja: I would agree.

Mr. Doug Eyolfson: Thank you.

To change topics a little bit, there is something that Sweden has in common with Canada. Right now, Sweden has one of Europe's largest elderly populations. This, of course, is expected to continue as birth rates are dropping. Canada has much the same issue. Our population is aging, and we're seeing the diseases that come with age. We're expecting increased health challenges and costs.

First of all, can you tell me if there are any preparations for how Sweden's system for pharmaceuticals and the health care system in general are going to manage these costs?

Ms. Sofia Wallström: Yes, there are.

The question is if there are enough and if they are targeting the right issues in time. Of course, there are discussions and preparations. When it comes to the pharmaceutical benefit scheme, I would not say that we do anything differently than we would have done otherwise. Other agencies in Sweden are focused on providing more guidelines, and they're working with issues when it comes to the elderly who use a lot of drugs. There have been governmental reforms targeted at reducing the number of pharmaceuticals that the elderly use, especially pharmaceuticals without good directions for people's health. That work has been going on for some years. We see that it will need to be enhanced further in the coming years.

● (1315)

Mr. Doug Eyolfson: Thank you so much.

Mr. Golja, do you have anything to add to that?

Mr. Aldo Golja: No. I would say the same.

There are programs right now for prescribers when it comes to appropriate use and prescribing guidelines for the elderly, especially, as you said, when it comes to the number of drugs that are interfering with each other, and things like that. Other than that, there is no [*Inaudible—Editor*].

Mr. Doug Eyolfson: Thank you very much.

The Chair: Thank you.

Now for our last question, we have Mr. Davies.

Mr. Don Davies: Thank you, Mr. Chair.

I'm interested in how each of your respective systems deals with the issue of high costs of specialty drugs for rare diseases. It's those kind of drugs that sometimes cost tens of thousands of dollars or a hundred thousand dollars a year. Has your system been able to provide those drugs to the patients who need them?

I'll start with you, Ms. Wallström.

Ms. Sofia Wallström: I would say that these drugs are a challenge. In the pharmaceutical benefits scheme, we haven't said no to a pharmaceutical for rare diseases except once in the last five to seven years. Many of these drugs are in-patient pharmaceuticals. That means that the TLV is not really responsible for the decisions. Of course, we give a lot of support, and we do have health technology assessments to support the county councils. We're all kind of together in the challenge when it comes to these specialty drugs.

We have a higher willingness to pay when it comes to effective drugs for rare diseases that are really severe and where there are no good alternatives. We have actually developed this further. Last year, the TLV said that we were willing to pay even more. We have managed to subsidize and reimburse the costs of the majority of these drugs. Still, there are a few that are really a problem for us, and we try to develop our own system for handling these. We see that more collaboration with other countries within the Nordic and European area is something that we need to move forward on.

Mr. Don Davies: Thank you, Mrs. Wallström. I'm just going to stop you there because I have limited time and I want to give Mr. Golja a chance to respond. Thank you.

Mr. Golja, go ahead.

Mr. Aldo Golja: I would agree. The savings on generics have allowed us, just like the Swedes, to buffer the additional growth in the prices of specialty drugs, so we've had a relatively flat budget for pharmaceuticals. This has also allowed us to take up the more expensive products, for instance, the orphan products.

However, for the orphan drugs, we're going to have managed entry agreements. As I said, this is based on the budgetary impact. If there is a large budgetary impact, we will engage in financial talks with the company before reimbursing those—that's also for out-patient drugs. Especially for orphan drugs with a high cost per patient, we will be asking the companies to engage in additional data collection, and also in finding the appropriate use, the right way of targeting the right population for these drugs. We are adding these things to our reimbursements.

We've been very lucky up to now to be able to do that, to incorporate most effective products in our reimbursement system, but it is increasingly a problem. That is also why, within the international realm, we've started collaborating with Belgium, Luxembourg, and Austria, just like the Nordic collaboration forum, where we are talking about pharmaceutical policies and where we engage in joint negotiations.

● (1320)

Mr. Don Davies: Thank you.

The Chair: Thanks very much.

That completes our testimony today. I want to thank our witnesses very much. You've taken a lot of time to help us. You've both submitted written presentations and taken a lot of time here today. You've been very helpful to give us a peek at two completely different programs. I am certain that, if Canada does eventually adopt a pharmacare program, you can both say that you've helped. On behalf of the committee, I want to say thank you very much.

I also want to thank the technicians, because everything today was flawless. The communications were flawless from three different countries, and that is no small feat.

I want to thank the committee for the great questions, and again, I want to thank you on behalf of the committee. Thank you very much for your time.

Ms. Sofia Wallström: Thank you.

Mr. Aldo Golja: Thank you.

The Chair: We're going to take a little break, and then do some committee business.

Mr. Oliver, go ahead.

Mr. John Oliver: I think this is our last meeting on pharma until we get the budget officer's report back. I have a procedural motion:

> That the analysts be directed to use the time period, as required, from today until Parliament resumes sitting in the fall, to complete a summary of evidence and testimony received so far in relation to the study of the development of a national pharmacare program, with a weighting to using peer-reviewed scientific evidence.

I put that forward as a motion so they can get started. We don't want to start cold in the fall when we get the parliamentary budget officer's report.

The Chair: We want them to be really busy all summer.

Mr. John Oliver: Absolutely.

Some hon. members: Oh, oh!

The Chair: Is there any debate or discussion on that motion, or any thoughts?

Ms. Karin Phillips (Committee Researcher): I want a little more clarification on the weighting toward peer-reviewed information. Obviously, I understand what peer-reviewed information is, but with written submissions, what we usually do is summarize all of the evidence, and then at the end of the day, when you give drafting instructions you can decide what you want or don't want included.

Mr. John Oliver: At the beginning, we had a number of presentations by witnesses with material they had put together that didn't seem to match or up or align with others. It wasn't peer-reviewed, and it didn't have the same rigour. It seemed to be more opinion than hard data. My motion is reflecting back on some of those earlier presentations.

The Chair: Some were almost anecdotal.

Karin, are you good?

Ms. Karin Phillips: What's challenging for us and the reason we summarize everything is that it's difficult for us to be put in a position of weighting a submission from one witness versus another. It's difficult to make those judgment calls, because it can become political, depending on whose witness it is.

The Chair: Dr. Carrie.

Mr. Colin Carrie: Maybe I could make a friendly amendment that you just do a summary of evidence and not worry about the weighting, and perhaps later on we could debate the political merits of one witness versus another.

We could take a break from that over the summer.

The Chair: Is that accepted?

Mr. John Oliver: Sure. I would take the advice from the analyst that it's hard for them to do that.

(Motion agreed to [See *Minutes of Proceedings*])

The Chair: We're going in camera to talk about witnesses for the thalidomide study, and we have to talk about Motion M-47, as well as Bill C-211 very briefly.

[*Proceedings continue in camera*]